PATENT ABSTRACTS OF JAPAN

(11)Publication number : 07-157610

(43)Date of publication of application : 20.06.1995

(51)Int.Cl. C08L 23/22
A61J 1/05
A61L 31/00
C08L 9/00
C08L 81/06
// A61M 5/178

(21)Application number : 05-309434

(22)Date of filing : 09.12.1993

(71)Applicant : DAIKYO SEIKO:KK

(72)Inventor : SUDOU MORIHIRO
KAWACHI EIJI
KAWACHI YASUSHI

(54) POLYSULFONE RESIN COMPOSITION AND UTENSIL MADE THEREFROM FOR MEDICAL AND MEDICINAL USE

(57)Abstract:

PURPOSE: To obtain a highly hygienic resin composition by forming a mixture or alloy containing at least one elastomer based on an isobuthylene/isoprene copolymer and at least one polysulfone resin.

CONSTITUTION: An isobutylene/isoprene copolymer rubber (referred to as IIR hereinafter), a rubber based on an isobutylene/isoprene copolymer, such as a chlorinated IIR, a polysulfone resin consisting of repeating units represented by the formula (ph-SO2-ph-S-)n (wherein (n) is 2 to 1,000; and ph is phenyl or phenylene), a vulcanizing agent such as sulfur, an organic peroxide or zinc oxide, a vulcanization accelerator, and a processing aid such as microcrystalline wax are mixed each in a prescribed amount. The mixture is kneaded by, e.g. a twin-screw extruder at about 120-380°C to give the objective composition comprising a mixture or alloy containing 99-1wt.% polysulfone resin and 1-99wt.% elastomer based on an isobutylene/isoprene copolymer. This composition is used for utensils for medical and medicinal uses, as a stopper body, an injector, a transfusion set, etc.

LEGAL STATUS

[Date of request for examination] 06.08.1997

[Date of sending the examiner's decision of rejection]	
[Kind of final disposal of application other than the examiner's decision of rejection or application converted registration]	
[Date of final disposal for application]	
[Patent number]	3065204
[Date of registration]	12.05.2000
[Number of appeal against examiner's decision of rejection]	
[Date of requesting appeal against examiner's decision of rejection]	
[Date of extinction of right]	

(19)日本国特許庁（ＪＰ）　(12)公開特許公報（A）　(11)特許出願公開番号

特開平7－157610

(43)公開日　平成7年(1995)6月20日

(51)Int.Cl.[6]	識別記号	庁内整理番号	ＦＩ	技術表示箇所
Ｃ０８Ｌ　23/22	ＬＣＺ			
Ａ６１Ｊ　1/05				
Ａ６１Ｌ　31/00	Ｃ			
			Ａ６１Ｊ　1/00　３１１	
			Ａ６１Ｍ　5/18	

審査請求　未請求　請求項の数９　ＯＬ　（全 12 頁）　最終頁に続く

(21)出願番号　特願平5－309434

(22)出願日　平成５年(1993)12月９日

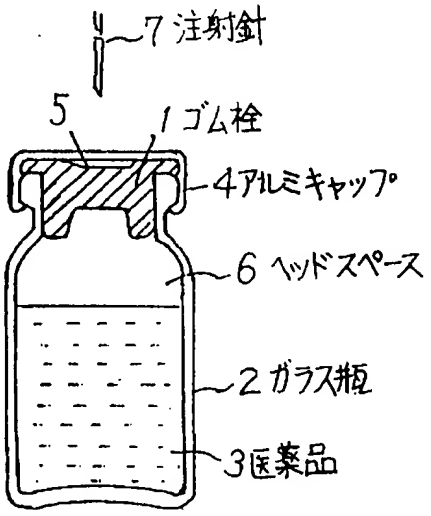
(71)出願人　000149000
株式会社大協精工
東京都墨田区墨田３丁目38番２号
(72)発明者　須藤　盛皓
東京都墨田区墨田３丁目32番７号
(72)発明者　河内　英治
群馬県桐生市境野町５丁目378番３号
(72)発明者　河内　康
栃木県足利市小俣町1740番地の13
(74)代理人　弁理士　内田　明　（外２名）

(54)【発明の名称】　ポリスルホン系樹脂組成物及びそれよりなる医療用，医薬品用器具

(57)【要約】

【目的】　医療用、医薬品用として好適な新規な樹脂組成物及びこれからなる医療用、医薬品用器具の提供。

【構成】　イソブチレン－イソプレン共重合系弾性体とポリスルホン系樹脂とを含有してなるポリスルホン系樹脂組成物及びこの組成物からなる医療用，医薬品用器具。衛生性が高く、例えば容器等の器具材料として用いてその内容物の長期保存に好適である。



【特許請求の範囲】

【請求項１】　イソブチレン－イソプレン共重合系弾性体とポリスルホン系樹脂とを含有してなるポリスルホン系樹脂組成物。

【請求項２】　イソブチレン－イソプレン共重合系弾性体の１種以上９９～１重量%とポリスルホン系樹脂の１種以上１～９９重量%とを含有してなる請求項１記載のポリスルホン系樹脂組成物。

【請求項３】　イソブチレン－イソプレン共重合系弾性体の１種以上とポリスルホン系樹脂の１種以上とを含有してなる混合物又はアロイ化物であることを特徴とする請求項１または請求項２に記載のポリスルホン系樹脂組成物。

【請求項４】　ポリスルホン系樹脂が（－Ｐｈ－SO_2－Ｐｈ－Ｓ－）$_n$〔但しｎは２～１０００の整数を意味する〕を繰り返し単位とするものであることを特徴とする請求項１ないし請求項３のいずれかに記載のポリスルホン系樹脂組成物。

【請求項５】　ポリスルホン系樹脂が（－Ｐｈ－SO_2－Ｐｈ－Ｏ－）$_n$〔但しｎは２～１０００の整数を意味する〕を繰り返し単位とするものであることを特徴とする請求項１ないし請求項４のいずれかに記載のポリスルホン系樹脂組成物。

【請求項６】　イソブチレン－イソプレン共重合系弾性体がイソブチレン－イソプレン共重合ゴム、塩素化イソブチレン－イソプレン共重合ゴム、臭素化イソブチレン－イソプレン共重合ゴム又はイソブチレン－イソプレン－ジビニルベンゼン共重合ゴムを含有することを特徴とする請求項１ないし請求項５のいずれかに記載のポリスルホン系樹脂組成物。

【請求項７】　請求項１ないし請求項６のいずれかに記載のイソブチレン－イソプレン共重合系弾性体とポリスルホン系樹脂とを含有してなるポリスルホン系樹脂組成物よりなる医療用，医薬品用器具。

【請求項８】　医療用，医薬品用器具が栓体であることを特徴とする請求項７記載の医療用，医薬品用器具。

【請求項９】　医療用，医薬品用器具が注射器，輸液セット又は容器であることを特徴とする請求項７記載の医療用，医薬品用器具。

【発明の詳細な説明】

【０００１】

【産業上の利用分野】本発明は衛生性が高く、例えば容器等の器具材料として用いてその内容物の長期保存に好適である新規なポリスルホン系樹脂組成物およびこの組成物からなる医療用，医薬品用器具に関する。

【０００２】

【従来の技術】医療用，医薬品用器具に関しては薬事法、日本薬局方及び厚生省告示に、その種類、性能、品質、試験項目、試験法、規格値などが定められている。今日のごとく医療技術が日進月歩の時代においては前記の各項目、方法及び数値にさらに要望事項としての各種規格値を加えた製品が製造されている。

【０００３】医療用，医薬品用に用いられる透明な素材は主として硝子製品であり、これに例えば密封するための軟質弾性体として天然ゴムを原料とする成形体を組合わせて器具としてきた。しかし近年は合成樹脂、合成ゴムを医療用，医薬品用器具の素材として検討され市販もされている。

【０００４】

【発明が解決しようとする課題】ところで従来汎用されている医療用，医薬品用器具素材については次のような特性と問題点がある。ポリ塩化ビニル（略称ＰＶＣ）は樹脂に添加される例えば錫系、カドミウム、亜鉛塩複塩化合物などの安定剤や、例えばジオクチルフタレート、ジオクチルアジペート、トリクレジルホスフェートなどの可塑剤などが、医薬品、薬液中に溶出し汚染すること。ＰＶＣ原料モノマーが樹脂中に残留していることの他に、樹脂製品を廃棄すると環境破壊を起こすことがある。ポリエチレン（略称ＰＥ）は軟化点が低い故に、それを素材とする製品は高圧蒸気殺菌できない器具となる。ポリプロピレン（略称ＰＰ）は高圧蒸気殺菌はできるが、高温殺菌は困難である。樹脂を変性し透明にして医療用素材とした報告がある（特開平３－１６３１４４、同３－２８２４６各号公報）。ＰＥ，ＰＰは水分、湿度に対する耐透過性は比較的優れているものの、酸素、炭酸ガス等の気体遮断性が悪く、内容薬物は酸化、変色する問題がある。このようなＰＥ，ＰＰの欠点を改善する方法として、エチレン、酢酸ビニル共重合成分のケン化物（略称ＥＶＯＨ）をＰＥ，ＰＰと混合するか、又はＰＥ，ＰＰとＥＶＯＨと積層した包装体にすることが提案されている（例えば「包装フイルム、成形容器、ボトルの実用耐熱性：プラスチックエージ 6号（1992年）、「ハイバリヤ多層プラスチック容器：製薬工場 vol.6, No.12(1986)」、「プラスチックのガスバリヤ性容器、プラスチックのガスバリヤ性と容器成形方法：フードパッケージング vol.32-No.3」、「ハイガスバリヤ性包装材料：プラスチック vol.38,No.5（1987)」、「バリヤ性樹脂容器への応用と現状：プラスチック vol.27, No.5（1977)」、「バリヤー性複合材料とＰＶＤＣ：コンパーテック vol.15, No.1（1987)」、「包装材を機能化するバリヤ樹脂：コンパーテック vol.17, No.6(1989)」、「最近の機能性包装材料：工業材料vol.37, No.14(1989)」、「最近の機能性包装容器の動向：科学と工業 vol.61-4(1987)」など）が、ＥＶＯＨは吸水、吸湿性が極めて強いために高圧蒸気殺菌時などに湿度、水分が共存すると、酸素、空気等気体遮蔽効力が極めて弱いという欠点を有する。硝子素材は耐熱、耐酸素性、透明性などに優れた素材であるが、ガラス表面から発生するアルカリや、硝子から剥離する微粒子が薬品、薬液を汚染するという問題点がある。ポリフェニレンエーテ

ル樹脂（略称ＰＦＥ）、ポリエチレンテレフタレート（略称ＰＥＴ）、ポリブチレンテレフタレート（略称ＰＢＴ）、ポリカーボネート（略称ＰＣ）の樹脂からは、悪臭、ホルムアルデヒド発生などの問題がある。天然ゴム（略称ＮＲ）及び合成ゴムのイソプレンゴム（略称ＩＲ）、ブタジエンゴム（略称ＢＲ）、スチレンーブタジエン共重合ゴム（略称ＳＢＲ）、ニトリルゴム（略称ＮＢＲ）、ブチルゴム（略称ＩＩＲ）及びハロゲン化ブチルゴム（ＢＩＩＲ，ＣＩＩＲ）などは医療用，医薬品用に使用する際に、ゴムを加硫する加硫剤、加硫促進剤及び補強剤が溶出、剥離などを起こして薬品、薬液を汚染する問題点がある。本発明者らは、すでにＩＲ，ＢＲ，ＳＢＲに超高分子量のポリエチレンを配合したゴム製品（特公平５－４３７４０号公報）、ＩＩＲに特殊な加硫剤を組み合わせたゴム製品（特開平４－２１３３４７号公報）を提案している。本発明は、従来品の欠点を解消した新規な素材を用いた医療用，医薬品用器具の提供を目的とするものであり、特に衛生性が高く、容器等の器具に用いて内容物への汚染物質溶出や剥離等がなく内容物の長期保存に適した新規なポリスルホン系樹脂組成物およびそれよりなる医療用，医薬品用器具を意図している。

【０００５】

【課題を解決するための手段】本発明は課題を解決するための手段として、イソブチレンーイソプレン共重合系弾性体とポリスルホン系樹脂とを含有してなるポリスルホン系樹脂組成物を提供する。本発明における特に好ましい態様として、イソブチレンーイソプレン共重合系弾性体の１種以上とポリスルホン系樹脂の１種以上とを含有してなる混合物又はアロイ化物であるポリスルホン系樹脂組成物が挙げられる。また本発明における特に好ましい態様として、該ポリスルホン系樹脂が（－Ｐｈ－SO_2－Ｐｈ－Ｓ－）$_n$〔但しｎは２～１０００の整数を意味する〕を繰り返し単位とするもの、あるいは（－Ｐｈ－SO_2－Ｐｈ－Ｏ－）$_n$〔但しｎは２～１０００の整数を意味する〕を繰り返し単位とするもの、であることが挙げられる。本発明は、さらに上記した本発明のイソブチレンーイソプレン共重合系弾性体とポリスルホン系樹脂とを含有してなるポリスルホン系樹脂組成物よりなる医療用，医薬品用器具を提供する。本発明の医療用，医薬品用器具の特に好ましい態様として、栓体が挙げられる。またさらに、本発明の医療用，医薬品用器具が注射器，輸液セット又は容器であることも特に好ましい態様である。

【０００６】

【作用】本発明に係るイソブチレンーイソプレン共重合系弾性体（以下、ＩＩＲ弾性体と略す場合もある）とは、イソブチレンーイソプレン共重合ゴム（ＩＩＲ）、イソブチレンーイソプレン共重合ゴムに塩素を反応させたゴム（ＣＩＩＲ）、イソブチレンーイソプレン共重合ゴムに臭素を反応させたゴム（ＢＩＩＲ）、イソブチレンーイソプレンージビニルベンゼン共重合ゴム（略称ＤＶＩＩＲ）の総称であり、ＩＩＲ，ＣＩＩＲ，ＢＩＩＲ，ＤＶＩＩＲを加硫剤例えば硫黄、亜鉛華、マグネシウム、アミン化合物、有機過酸化物、マイミド化合物等から選ばれる１種以上を用いて加硫してなる弾性体である。

【０００７】本発明に係るＩＩＲ弾性体はイソプレン基含有量４．５重量%以下、平均分子量10,000～650,000であり、例えばＩＩＲの１００重量部に対して、硫黄、例えばｔ－ブチルペルオキシイソプロピル、ｎ－ブチル－４，４′－ビス（ｔ－ブチルペルオキシド）バレレート、１，１－ジ（ｔ－ブチルペルオキシ）３，３，５－トリメチルシクロヘキサンなどの有機過酸化物、例えばＮ，Ｎ′－ｍ－フェニレンビスマレイミドなどのマレイミド類、亜鉛華などの加硫剤及び例えばジペンタメチレンチウラムテトラスルフィド、ジエチルジチオカルバミン酸亜鉛、テトラメチルチウラムモノスルフィド、テトラメチルチウラムジスルフィドなどの加硫促進剤を０．５～２重量部加えて例えば加熱加圧することにより加硫する等の公知手段により製造することができる。

【０００８】本発明に係るＢＩＩＲ，ＣＩＩＲの弾性体は、ＢＩＩＲ，ＣＩＩＲの１００重量部に対して、亜鉛華、酸化マグネシウム、例えば分子内にアミノ基とカルボキシル基とを有する有機アミン化合物等の加硫剤、前記ＩＩＲ弾性体の場合と同様の加硫促進剤等を１～５重量部添加して加熱、加圧することにより製造できる。

【０００９】本発明に係るＤＶＩＩＲの弾性体は、ＤＶＩＩＲ１００重量部に対しＩＩＲの弾性体と場合と同様の有機過酸化物を０．５～２重量部配合し、加熱、加圧して加硫することにより製造できる。

【００１０】本発明に係る弾性体の加硫、本発明の樹脂組成物の調製及び該組成物からの成形の具体的手法として、生ゴムに上記のような各種配合剤を予め混合した後、インターナルミキサーまたは混合押し出し加工機にて１６０～２２０℃にて加圧、加熱する動的なる加硫を行った後に、ポリスルホン樹脂に混合し、又は混合、アロイ化する方法、あるいは加硫剤の他に加硫促進剤を配合しさらにポリスルホン酸を配合し金型内にて成形加硫する方法等を採用することができる。

【００１１】本発明に係るポリスルホン系樹脂とは、芳香族系炭化水素基とスルホニル基（－SO_2－）との結合を主成分とした超高分子体の樹脂である。該芳香族炭化水素基としてはフェニル基、フェニレン基が挙げられる。スルホニル基１個に結合するフェニル基又はフェニレン基は１個の場合と２～７個のものがあり、後者の場合にはビフエニル基、ビスフェニルアルカン基、トリフェニル基などである。また、本発明のポリスルホン系樹脂は構成成分としてフェニル基、フェニレン基又はスルホニル基の他に、オキシ基（－Ｏ－）、チオ基（－Ｓ

－）、カルボニル基（－ＣＯ－）、メチル基等の低級アルキル基を有することができる。

【００１２】本発明に係るポリスルホン系樹脂の繰り返し単位の具体例を以下に挙げる。以下の例ａ～ｗにおいて、略号は次のとおりを意味する。Ｐｈ：フェニル基又はフェニレン基、－SO_2－：スルホニル基、－Ｏ－：オキシ基、－Ｓ－：チオ基、－ＣＯ－：カルボニル基、CH_3－：メチル基。ｎ：２～１０００の整数

ａ：$(-Ph-SO_2-)_n$

ｂ：$(-Ph-SO_2-Ph-)_n$

ｃ：$(-Ph-SO_2-Ph-Ph-SO_2-Ph)_n$

ｄ：$(-Ph-SO_2-Ph-Ph-Ph-SO_2-Ph)_n$

ｅ：$(-Ph-SO_2-Ph-Ph-Ph-SO_2-)_n$

ｆ：$(-Ph-SO_2-Ph-O-)_n$

ｇ：$(-Ph-SO_2-Ph-SO_2-Ph-O-)_n$

ｈ：$(-Ph-SO_2-Ph-SO_2-Ph-O-Ph-O-)_n$

ｉ：$(-Ph-SO_2-Ph-PhSO_2-Ph-O-)_n$

ｊ：$(-Ph-SO_2-Ph-Ph-SO_2-Ph-O-Ph-O-)_n$

ｋ：$(-Ph-SO_2-Ph-Ph-SO_2-Ph-O-Ph-Ph-O-)_n$

ｌ：$(-Ph-SO_2-Ph-Ph-O-Ph-O-)_n$

ｍ：$(-Ph-SO_2-Ph-O-Ph-O-Ph-O-)_n$

ｎ：$(-Ph-SO_2-Ph-O-Ph-Ph-O-)_n$

ｏ：$(-Ph-SO_2-Ph-CH_2-Ph-SO_2-Ph-O-)_n$

ｐ：$[-Ph-SO_2-Ph-Ph-O-Ph-C(CH_3)(CH_3)-Ph-O-]_n$

ｑ：$[-Ph-SO_2-Ph-O-Ph-C(Ph)(Ph)-Ph-O-]_n$

ｒ：$(-Ph-SO_2-Ph-S-)_n$

ｓ：$(-Ph-SO_2-Ph-O-Ph-CO-Ph-O-)_n$

ｔ：$(-Ph-SO_2-Ph-O-Ph-O-)_n$

ｕ：$[-Ph-SO_2-Ph-O-Ph-C(CH_3)(CH_3)-Ph-O-]_n$

ｖ：$(-Ph-Ph-SO_2-Ph-Ph-SO_2-Ph-O-)_n$

ｗ：$[-(CH_3)(CH_3)-Ph-SO_2-Ph(CH_3)(CH_3)-O-Ph-CO-Ph-O-]_n$

【００１３】本発明に係るポリスルホン系樹脂は前記したような繰り返し単位を主成分とする重合体であり、従来公知の技術、例えば特公昭４５－２１３１８、同４６－２１４５８、同４７－６１７、同５３－２５８７９、同５６－２０９１、同６１－１２９３０、特開昭５２－９６７００、同５３－１０６９６、同５９－１２９３０、同６３－２１０３０、同６３－２４３１２８、特開平１－３１５４２２、同１－３１８０４０、同３－４１１２０、同３－９５２００、同４－３３５０３０、同５－９４５３各号公報等に記載される技術により重合して製造できる。該ポリスルホン系樹脂の平均分子量は 5,000～950,000 であり、該樹脂は極性有機溶媒中でアルカリ性触媒を使用して重合すること方法が多く採用されている。ただし本発明に使用するポリスルホン系樹脂は、溶媒洗浄、温水洗浄などを繰り返して、原料化合物、低分子量のオリゴマー、無機化合物（多くはＮａＣｌ）等をできるだけ除去したものが好ましい。このような該ポリスルホン系樹脂の精製手段には各種の公知技術を適用できる。本発明に係るポリスルホン酸系樹脂は強靭性、高強度、耐熱性、耐クレープ性、耐摩耗性であり、淡白色、透明性の樹脂であって、酸、アルカリ、塩溶液にも優れた耐性を有し、洗剤、炭化水素中での高温条件にも耐え得る。さらに、耐スチーム、耐熱水性で１３０℃，３０分間のオートクレーブ滅菌にも繰り返し耐え得る特性を有するので、医療用，医薬品用器具に利用して非常に有利である。

【００１４】なお、本発明のポリスルホン酸樹脂としては比較的高分子量の安定剤を添加したものが好ましい。このような安定剤としては、例えばテトラキス〔メチレン（３，５－ジ－ｔ－ブチル－４－ヒドロキシフェニル）プロピオネート〕メタン：商品名イルガノックス１０１０（チバガイギー（株）製）、トリエチレングリコール－ビス－３－（２－ｔ－ブチル－４－ヒドロキシ－５－メチルフェニル）プロピオネート：商品名イルガノックス２４５（チバガイギー（株）製）、ビス（２，６－ジ－ｔ－ブチル－４－メチルフェニル）ペンタエリストールジホスファイト：商品名アデオスタブＰＥＰ－３６（旭電化（株）製）、Ｎ，Ｎ′－ｍ－フェニレンビスマレイミド、トコフェロールなどが挙げられ、これらの１種類以上を該ポリスルホン酸樹脂１００重量部に対し０．０１～０．５重量部添加することが好ましい。

【００１５】本発明の組成物は上記したＩＩＲ弾性体とポリスルホン系樹脂を含有してなる。また、該ＩＩＲ弾性体とポリスルホン系樹脂は各々１種以上を配合することもできる。ＩＩＲ弾性体に対しポリスルホン酸系樹脂を９９～１重量%、好ましくは９５～５重量%の範囲で配合する。この配合割合は医療用，医薬品用器具の種類、その器具に適する硬軟の度合いに対応して選択することが望ましい。例えば医療用，医薬品用器具栓体として適用する場合には、ＩＩＲ弾性体１００重量部に対し、ポリスルホン酸系樹脂を５～４０重量部配合することが好ましい。特に好ましくは５～３０重量部である。

これは５重量部未満では所期の目的に対し好適な特性例えば弾性を得られず、４０重量部を越えると栓体としての物理的特性、例えば注射針刺しの際に必要とされる物理的特性を欠くことになるからである。また、医療用，医薬品用器具の容器本体等に使用する場合には、ポリスルホン酸１００重量部に対してＢＩＩＲ，ＣＩＩＲ，ＤＶＩＩＲから選ばれる弾性体を２～１００重量部、好ましくは５～５０重量部を混合、又はアロイ化する。耐熱性、高弾性の樹脂体となり、医療用器具、医薬品用器具として耐熱性が高く、従って熱殺菌、高圧オートクレブ殺菌、エチレンオキサイド殺菌を繰り返し行い得る容器，器具となる。従って、手術用器具、注射器、注射器兼容器等に成形して好適である。またフィルムにして輸液用袋類等の素材に用いることができ、ブドウ糖、アミノ酸を含有する高タロリー輸液剤の保存容器などにも好適に用い得ることが判明した。該フィルム成形の場合には本発明の組成物に加工助剤、グラフト共重合体等を混合することが好ましい。

【００１６】前述のように本発明のＩＩＲ弾性体とポリスルホン樹脂からなる組成物は混合物であってもよいし、アロイ化物とすることもできる。また、混合物、アロイ化物の加工性、成形性を良好にするために加工助剤を添加することができる。このような加工助剤としては、例えば高級脂肪酸類：例えばアラキン酸、ベヘン酸等、金属石ケン類：例えばステアリン酸亜鉛、ステアリン酸カルシウム、ステアリン酸アルミニウム塩など、脂肪酸アミド類：例えばスチレンビスステアリルアミド、エチレンビスオレイン酸アミド、ベヘン酸アミド、ステアリン酸アミドなど、高級脂肪酸エステル類：例えば炭素数２０～２４個の長鎖脂肪酸エステル、ソルビタン脂肪酸エステルなど、ワックス類：例えばマイクロクリスタリンワックス、ポリエチレンワックスなど、高分子量ポリエチレン類、炭素数１６～１８個のアルコール類、シリコンオイル類等の１種類以上を１０重量部以下、グラフト共重合体、ブロック共重合体（例えば、ブタジエン－スチレン－ブロック共重合体及び該共重合体の水素添加物、ポリジメチルシロキサン－ポリエチレンオキシドブロック共重合体、エチレン－グリシジルメタクリレートグラフト共重合体など）などから選ばれる１種類以上を２０重量部以下配合することによって非常に均一なアロイ化物とすることができ、加工性を改善することができる。

【００１７】本発明に係るＩＩＲ弾性体とポリスルホン系樹脂とを混合、混練してアロイ化する手段としては、従来公知の装置、例えばインターナルミキサー、一軸又は二軸押出機を用いて、温度１２０～３８０℃にて行なうことができ、均一な混合物、アロイ化物となる。また、そのまま押出成形して医療用，医薬品用器具とすることもできる。本発明に係る医療用，医薬品用器具として成形した製品は、いずれも日本薬局方（第１２改正）の４８．輸液用ゴム栓試験法、４９．輸液用プラスチック容器試験法、厚生省告示第３０１号、同４１３号、同４４２号に適合する医療用，医薬品用器具であり、注射器、注射器兼容器、輸液セット器具とすることができる。また医薬品、薬液の容器として内容薬品を長期に渡りその品質を保持し得るという優れた特徴を有する容器となる。

【００１８】

【実施例】以下、本発明を実施例により詳細に説明するが、本発明はこれらに限定されるものではない。

〔ポルスルホン酸の重合：１〕10,000mlのオートクレーブにＮａＨＳ（濃度４７重量%）３５８ｇ、ＮａＯＨ（濃度４８重量%）２２５ｇ、CH_3COONa １２３ｇ、Na_2CO_3 １９ｇ及びＮ－メチルピロリドン２３７６ｇを仕込み、窒素ガスを流しつつ温度１３０℃にて３時間撹拌する。その混合物を７０℃に冷却した後に、該反応物中にＮ－メチルピロリドン２９７ｇと４，４－ジクロロジフェニルスルホン８７８．５ｇとの混合物を撹拌しつつ混入し、温度２６０℃にて４時間加熱して重合を行なう。次に１℃／分の速さにて１２０℃まで撹拌しつつ冷却し、酢酸９ｇとＮ－メチルピロリドン２５８３ｇの中に撹拌しつつ徐々に流し込み、重合体を微粒子粉末状として析出せしめ、濾別した後に７０℃の温水1500mlにて洗浄、さらにメタノール1000mlにて洗浄する。得られた重合体１００重量部にイルガノックス１０１０　０．１重量部を添加後、真空にて乾燥する。得られた樹脂量６３２ｇ、ガラス転移温度１９２℃であった。該樹脂は淡黄色透明で、繰り返し単位は（－Ｐｈ－SO_2－Ｐｈ－Ｓ－）$_n$、すなわち前記した繰り返し単位ｒであった。該樹脂を樹脂ｒと略す。

【００１９】〔実施例１～３及び比較例１，２〕ＩＩＲ〔商品名　ＪＳＲ　Ｂｕｔｙｌ　３６５、日本合成ゴム（株）製、不飽和度２．０モル%、ML_{1+8} 100℃　４２〕１００重量部に対して、前記で得たポリスルホン樹脂ｒを下記の表１に示す比率（表中の部は重量部を意味する）で配合し、インターナルミキサー、二軸押出機にて混練し、二本ロールにて分出しして配合生地を作成した。

【００２０】

【表１】

配　合	実施例１	実施例２	実施例３	比較例１	比較例２
ＩＩＲ	100 部	100 部	100 部	100 部	100 部
樹脂ｒ	5	2.5	5	① 10	② 25
加硫剤　③	1.5	1.5	1.5	1.5	1.5
加硫促進剤　④	2	2	2	2	2
ワックス　⑤	3	3	3	3	3
⑥	－	－	1	－	－

【００２１】上記表１の①～⑥は次の通り。

①ＰＥ：低密度ポリエチレン、ショウレックスＭ２２２、昭和電工（株）製、軟化点９２℃。

②充填剤：商品名　Ｗｈｉｔｅｔｅｘ：Ｓｏｕｔｈｅｒｎ　Ｃｌａｙ社製。

③２，５－ジメチルー２，５－ジ（ｔ－ブチルペルオキシ）ヘキサン。

④Ｎ，Ｎ′－ｍ－フェニレンビスマレイミド。

⑤マイクロクリスタリンワックス（融点１１０°Ｆ、日本精蝋（株）製）。

⑥γ－メルカプトトリメトキシシラン：日本ユニカー製Ａ－１８９（商品名）。

【００２２】上記で得た配合生地をオシレイティング・ディスクレオメーター（Ｏ．Ｒ．Ｒ．と略称する）試験機で、日本ゴム協会誌VOL.４０（１９６７）ｐ８７４、ＡＳＴＭ　Ｄ－２７０５、ＳＲＩＳ　３１０２　により振動式加硫試験〔回転往復運動の微小角振動（ねじり振動）を与えて、その対応する応力をトルク値として測定し、トルク最高値（ｃ）を求め、これとトルク最低値（ｂ）との差を求める〕を行い、その結果を表２にまとめて示す。

【００２３】

【表２】

	項　　目		実施例１	実施例２	実施例３	比較例１	比較例２
試験結果	スコーチ時間　(分)		3.0	3.1	3.0	2.9	2.6
	加硫時間(分)		8.9	9.3	8.8	8.9	8.5
	トルク値 (kg/cm)	最低値 (b)	9.6	10.1	9.4	8.8	9.6
		最高値 (c)	21.8	23.5	22.5	16.3	18.2
		(c)－(b)	12.2	13.4	13.1	7.5	8.6
	加硫ゴム片のカタサ(Hs)		35	40	38	24	28

【００２４】表２に示す如く、実施例１は比較例１，比較例２の生地よりもトルク値[(c)－(b)]の差が大きく、カタサも大きいのでゴムが高弾性体であることがわかる。また樹脂Ａを増量した実施例２、シランカップリング剤を添加した実施例３では、それぞれその添加効果により実施例１よりも高いトルク値とＨｓ値を示している。

【００２５】次に上記で得た各生地を用いて、図１に示す医薬品用ゴム栓を加硫条件：温度１７０℃、１０分間：で成形した。なお、図１は該ゴム栓をガラス瓶に適用した一具体例の概略断面図でありガラス瓶２にゴム栓１を打栓してアルミキャップ４で巻き締めた状態を示し、３は医薬品、５は針入部、６はヘッドスペース、７は注射針を示す。各ゴム栓について第１２改正日本薬局方の試験法及び、本発明者らが実用している特殊な衛生試験を行った。その結果を表３及び表４に示す。特殊な衛生試験は次のように行なう。

【００２６】その他の特殊な衛生試験

微粒子量（ゴム栓より発生する粒子量の試験）；硬質ガラス瓶中にゴム栓１０個を入れ、無塵水３００ml加えて、容器口をフィルムで包み、手にて２回転／秒程度にて２０秒間振動する。その後１時間静置してから光遮蔽型自動微粒子計測器（ＨＩＡＣ社製）にて水中の微粒子の個数を測定する。なお、注射液中の５μｍ以上の微粒子の存在は血管を閉塞する等の問題を起こすので重要項目となっている。

【００２７】ゴム破片の剥離（Ｆｒａｇｍｅｎｔａｔｉｏｎ）；図１に２として示す形状の瓶（１０ml容量）に

水５mlを入れ、ゴム栓１を打栓し、次にアルミキャップ４を巻き締める。試験針〔２２Ｇ（０．７０×３２mm）〕を付けた注射筒に２mlの水を入れ、これをゴム栓の針入部５に２０回貫通させる。２０回目の貫通時に注射筒内の水を瓶内に注入した後注射針を引き抜く。瓶内を振動したのち、ゴム栓を取り除き、内容液をろ過し、濾紙上のゴム片個数を数える。本試験法は、ブリティッシュスタンダード３２６３（ＢＳと略す）の方法を改良したもので、ＢＳの規格はゴム片３個以下であるが、現在当該業界では２個以内が要望されている。

【００２８】薬液漏れ；図１の瓶２に水５００mlを入れ、ゴム栓１を打栓し、アルミキャップ４を巻き締める。これを容器内にて１２１℃に３０分間加熱した後、ゴム栓の針入部５よりロケット針７（ＪＭＳ性２００号、輸液セット付ロケット針）を刺し通し、瓶を倒立状態に保ちながら１時間放置し、次に空気針を刺し、瓶内の水を４００ml流出せしめ、この時点でゴム栓からロケット針を引抜き、このときの液漏れ（ml）を観察、測定する。

【００２９】撥水性（Ｗａｔｅｒ　ｒｅｐｅｌｌｅｎｃｙ）；図１の瓶２に蒸留水５００mlを入れ、ゴム栓１を打栓し、アルミキャップ４を巻き締める。次に耐圧加熱容器に入れ、温度１２１℃で３０分間蒸気処理し、２４時間室温に放置した後、瓶内壁を観察する。このとき水滴を認めないものを合格とする。

【００３０】注射針刺し抵抗力試験（Ｄｅｔｅｒｍｉｎａｔｉｏｎ　ｏｆ　ｐｅｎｅｔｒａｂｉｌｉｔｙ）；注射針７（２１．Ｓ．Ｗ．Ｇ．外径0.81mm、長さ３８mm）が２０cm／分の速度でゴム栓を貫通する時の力を測定機（テンション形ゴム引張試験機）で測定し、0.5 kgで合格とする。本試験はＢＳの相当する試験の改良である。ＢＳ規格値は１０００ｇ以下で合格。

【００３１】水蒸気透過性試験図１のガラス瓶中に２重量%食塩水溶液８mlを入れ、ゴム栓１を打栓し、さらにアルミキャップ４を巻き締める。このガラスびんをシリカゲルを入れたデシケーター中で室温にて６ケ月間保存後、重量の変化を測定して、ゴム栓の水蒸気透過量（ｇ）を測定する。５本の平均値を取り、１ｇ以下を合格とする。本発明者らの自主規格試験である。

【００３２】ヘッドスペース中のガス成分試験
図１のガラス瓶２中に２重量%食塩水溶液８mlを入れ、ゴム栓１を打栓し、更にアルミキャップ４を巻き締める。このガラス瓶を耐圧容器にて温度１２１±１℃にて６０分間蒸気加熱した後、約１０時間放置する。次にガス用シリンジにて瓶内のヘッドスペース６のガス５mlを採取し、これをガスクロマトグラフ法にて測定する。カラム：１０%ＯＶ－１０１（１８０～２００メッシュＷＨＰ）、キャリヤーガスＨｅ５０ml／分、カラム温度１００～２００℃（4℃／分昇温）、のピークの有無、大小を見る。本試験は近年問題になっているゴム及び配合剤による極微量ガス発生を調べる試験である。

【００３３】耐アルカリ溶液試験；耐アルカリ容器にゴム栓１０個を入れ、ゴム栓重量の１０倍量の炭酸ソーダ0.5 重量%溶液を加えた後、該ゴム栓を打栓してアルミキャップを巻き締める。次に高圧容器にて温度１２１℃にて３０分間蒸気加熱する。室温まで放置、冷却後ゴム栓を除き、試験液を石英セルにて波長４３０nmと６５０nmの可視部の透過率を測定する。９５%以上を合格とする。本試験は、ゴムと薬液との関係を試験する基本的な試験で透過率の低いゴム製品は採用不適である。

【００３４】吸水試験；架橋成形したゴム製品を温度１０５℃常圧で３時間乾燥する。次に乾燥剤入りのデシケーター中に約１時間放置後その重量(A) を精秤する。次に該ゴム栓の１０倍量の精製水中に浸し、そのまま耐圧容器内で温度１２１±１℃、３０分間蒸気加熱する。冷却後、ゴム栓のみをデシケーター中に３０分間放置して表面の水を取り、その時の重量(B) を精秤し、([(B)－(A) ／(A)]×１００)(%) を求め、２重量%以下を合格とする。

【００３５】薬液の吸着試験；硝酸イソソルビト（虚血性心疾患用薬、融点７２℃、日本製薬製）を生理食塩水で希釈して０．０４０重量%として、この液３mlを正確に１０ml瓶２に入れ、ゴム栓を打栓し、アルミキャップを巻き締めて、倒立状態にて２４時間放置した。これを高速液体クロマトグラフ（ＨＬＰＣ製）にかけ、硝酸イソソルビトの量を測定して、吸着した減量を得る。カラム：ＦＩＮＥＰＡＫ　ＳＩＬＣ１８（商品名、日本分光製）、移動相メタノール：水＝７：３、流速１ml／分、検出器ＵＶＩＤＥＣ１００－ＩＶ（商品名、日本分光製、２２０ｎｍ）

【００３６】

【表３】

		実施例１	実施例２	実施例３	比較例１	比較例２	第12改正日本薬局方、ＤＩＮ規格合格値
第	性状（％）	99.5	99.5	99.5	99.5	99	99.0
改	泡立ち	2分未満	2分未満	2分未満	2分未満	3分	3分以下
正	ｐＨ	0.7	0.8	0.7	0.9	1.1	±1.0以下（ブランクとの差）
日	Ｚｎ（ppm）	1未満	1未満	1未満	1未満	1未満	1 ppm以下
本	$KMnO_4$還元性(ml)	1.3	1.5	1.4	1.8	2.0	2.0 ml以下
薬	蒸発残留物（ｍｇ）	1.0	1.3	1.1	2.0	2.2	2.0 mg以下
局	紫外吸収スペクトル	0.10	0.12	0.11	0.13	0.15	0.2以下［波長 220～350nm］
方	急性毒性試験	適合	適合	適合	適合	適合	適合
試	発熱性試験	適合	適合	適合	適合	適合	適合
験	溶血性試験	適合	適合	適合	適合	適合	適合

加硫条件（温度１７０℃×１０分）

【００３７】

【表４】

		実施例１	実施例２	実施例３	比較例１	比較例２	第12改正日本薬局方、ＤＩＮ規格合格値
	微粒子量(5μm以上の個数)	3	5	2	7	13	
特	ゴム破片の剥離(個数)	0	0	0	1	5	3個未満（ＤＩＮ規格NO　）
殊	薬液漏れ(ml)	0	0	0	0	0	
な	撥水性	なし	なし	なし	なし	なし	
衛	注射針刺し抵抗力試験(kg)	0.2	0.4	0.3	0.1	0.3	
生	水蒸気透過性試験	0.5	0.6	0.5	1.4	1.2	
試	ヘッドスペース中のガス成分試験	小	小	小	小	小	
験	耐アルカリ溶液試験	99	99	99	99	98	
	吸水試験	0.3	0.4	0.3	0.2	0.5	
	薬液の吸着試験	1.2	1.5	1.2	1.2	1.7	

加硫条件（温度１７０℃×１０分）

【００３８】表３、表４に示すごとく、本発明品は全て第１２改正日本薬局方の規格値に適合している。それに加え、最新の医薬品に対応できる容器、器具としての特殊な自主試験項目にも適合できる優れたゴム栓であることがわかる。一方比較例１，２の製品は例えばｐＨ、蒸発残留物、微粒子量などの数項目において問題となる結果を示している。

【００３９】〔実施例４〕ＢＩＩＲ（ＥＸＸＯＮ　ＣＨＥＭＩＣＡＬ社製、ML_{1+8}　１２５℃　５０、臭素含有量０．６重量％）１００重量部、活性亜鉛華（堺化学工業株）製）１．０重量部、Ｎ，Ｎ′－ｍ－フェニレンビスマレイミド（川口化学工業（株）製）２．０重量部、不溶性硫黄（日本乾溜（株）製０．２重量部をインターナルミキサーで混合した後に、温度１６０℃で７分間混練を行い、動的加硫物とした。別に精製したポリスルホン樹脂（商品名　ＵＤＥＬ　ＰＯＬＹＳＵＬＦＯＮＥ、ユニオンカーバイド社製の繰り返し単位が前記ｕ：〔－Ｐｈ－SO_2－Ｐｈ－Ｏ－Ｐｈ－Ｃ（CH_3）（CH_3）－Ｐｈ－Ｏ－〕$_n$を、Ｎ－メチルピロリドン：水＝１：０．５を加熱してなる溶媒で２回洗浄したもの〕１００重量部、エチレンビスステアリン酸アミド（日本化成（株）製）１重量部、スチレン－ブタジエン－エチ

レン共重合体を無水マレイン酸５重量部　ブロック共重合体（試作品）５重量部をインターナルミキサー及び二連式押出機にて温度１６０～２２０℃でアロイ化物とした。次にTタイを通して均一なるフィルム板とした。厚さ０．４mm。ＪＩＳ　Ｋ６３０１に準拠して物理的性質を測定した結果、引張り強さ２１３kg/cm^2、伸び２１０%であり，酸素ガス透過量を測定（柳本製作所製ＧＴＲ製）したところ、温度２０℃、乾燥状態では１００cc/m^2 ・２４hrs/atm であった。混練前のＢＩＩＲの加硫したフィルム板の酸素ガス透過量は３００cc/m^2 ・２４hrs/atm であったことから、本発明によればＩＩＲ弾性体とポリスルホン樹脂を混合することにより酸素に対するガスバリヤー性が改良されたことがわかる。なお、本発明のＢＩＩＲとポリスルホン酸樹脂とのアロイ化物について第１２改正日本薬局方の４９．輸液用プラスチック容器試験法に準拠した試験を行い、その結果を後記の表５に示す。

【００４０】〔実施例５〕ＣＩＩＲ（ＪＳＲ　CHLOROBUTYL　１０６８、商品名、日本合成ゴム（株）製、ML$_{1+8}$ １２５℃　５０、ハロゲン含量１．２重量%）１００重量部、活性亜鉛華（堺化学工業（株）製）１．０重量部、ジエチルジチオカルバミン酸亜鉛１．０重量部をインターナルミキサーで混合した後に温度１６０℃で７分間混練を行い、動的加硫物とした。別に精製したポリスルホン酸〔商品名ＶＩＣＴＲＥＸ　ＰＥＳ、ＩＣＩ社製、繰り返し単位が前記ｆ：（－Ｐｈ－SO_2 －Ｐｈ－Ｏ－）$_n$ のものを、テトラヒドロフラン：水：酢酸＝２０：５：０．１の加熱した溶媒にて洗浄後にアセトンでさらに洗浄したもの〕４００重量部、スチレン－エチレン－スチレンブロック共重合体（シイルケミカル社扱い品）１０重量部、ポリエチレンテレフタレート（クラレ（株）製ポリエチレンテレフタレート、グレードＫＳ７００）３０重量部をインターナルミキサー及び二連式押出機にて温度１６０～２２０℃でアロイ化物とした。次にTタイを通して厚さ０．４mmの均一なるフィルム板とした。該フィルムについてＪＩＳ　Ｋ６３０１に準拠して物理的形質を測定した結果、引張強さ２５６kg/cm^2、伸び１８０%であり，酸素ガス透過量を実施例４と同様に測定したところ、８５cc/m^2 ・２４hrs/atm であった。作成した輸液剤容器を図２に示す。図２において８は注射液、９は容器口部、１０は溶着栓、１１は熱溶着部、１２は懸垂けを表す。なお、第１２改正日本薬局方の４９．輸液用プラスチック容器試験法に準拠した試験を行い、その結果を後記の表５にあわせて示す。表５に示す如く、本発明による製品は第１２改正日本薬局方の規格値に合格している。

【００４１】

【表５】

項　　目	実施例４	実施例５	薬局方規格合格値
性状（%）［波長220-350nm］	99.5	99.5	無色透明
泡立ち	1 未満	1 未満	3 分以内
pH	0.8	0.7	±1.5 以内
塩化物（ppm）	1	3	－
硫酸塩（ppm）	0.1	0.2	－
リン酸塩（ppm）	0.1	0.1	－
アンモニウム塩（ppm）	0.2	0.2	－
$KMnO_4$ 還元性（ml）	0.8	0.6	1.0 以下
蒸発残留物（mg）	0.3	0.4	1.0 以下
紫外吸収スペクトル	0.03	0.04	0.05 以下
急性毒性試験	適合	適合	適合
発熱性物質試験	適合	適合	適合
溶血性試験	適合	適合	適合

【００４２】〔ポリスルホン酸の重合：２〕３０００ｍｌの三口フラスコにビス（３，５－ジメチル－４－ヒドロキシフェニル）スルホン　３０６ｇ（１モル）、クロルベンゼン１０００ｍｌ、スルホラン４５０ｍｌを添加し、撹拌し、窒素ガス雰囲気下に６０℃に加熱し、ＮａＯＨ（４５重量%）溶液２５０．５ｇを徐々に加え、５０ｍｌの精製水を加えて共沸によってクロルベンゼンを除き、温度１２０～１４０℃まで加熱を続け、反応物が１４５℃に達したならば１３０℃に冷却し、ビス（４－フルオロフェニル）ケトン　２１８ｇを加え、２００℃にて８時間反応する。重合反応物は冷却し、多量のメタノールを撹拌下に注ぎ、樹脂を析出させ、濾過し、アセトン、温水で洗浄して真空乾燥した。樹脂量４５０ｇ　繰り返し単位　ｗ：〔－（CH_3）（CH_3）Ｐｈ－SO_2 －Ｐｈ（CH_3）（CH_3）－Ｏ－Ｐｈ－ＣＯ－Ｐｈ－Ｏ－〕$_n$ 、ガラス転移温度２４０℃。この樹脂を樹脂ｗと略す。

【００４３】〔ポリスルホン酸の重合：３〕４０００ｍ

1の三口フラスコに4，4′－ジフェノール１４９ｇ、4，4′－ジクロロジフェニルスルホン２３４ｇ、無水炭酸カリウム１２１．６ｇ、N，N′－ジメチルアセトアミド１２００ｇを仕込み、反応器内を窒素ガス雰囲気にし沸騰させて、N，N′－ジメチルアセトアミドと水を流出させる。約４時間重合反応を行った後、冷却し、炭酸カリウムを濾別し、多量のメタノールを撹拌下に注ぎ、樹脂体を析出させ、メタノール、温水で洗浄して真空乾燥を行なう。得られた樹脂量は３４０ｇ。ガラス転移温度２２０℃。該樹脂は繰り返し単位が前記ｎ：（－Ｐｈ－SO_2－Ｐｈ－Ｏ－Ｐｈ－Ｐｈ－Ｏ－）$_n$であり、該樹脂を樹脂ｎと略す。

【００４４】〔実施例６～１０〕各種のポリスルホン樹脂及びＩＩＲ弾性体について、表６に示す比率（重量部）に配合した。予め各原料粉末にて混合した後、押出機温度１８０～２２０℃にて動的加硫後に図３に示す注射筒形状に成形した。図３において１３は注射筒、１４は滑栓、１５は注射針、１６は押子棒を表す。得られた注射筒について厚生省告示第４４２号に準拠して試験を行った。結果を表７に示す。

【００４５】

【表６】

		実施例 6	実施例 7	実施例 8	実施例 9	実施例 10
本発明のポリスルホン樹脂組成物配合（重量部）	ポリスルホン樹脂	n 100 —	w 100 —	u 80 f 20	f 80 n 20	f 100 —
	ＩＩＲ弾性体ゴム	BIIR 10	CIIR 5	DVIIR 20	DVIIR 15	DVIIR 15
	その他の配合剤 活性亜鉛華[a]	0.5	0.5	—	—	—
	その他の配合剤 アデオスタブＰＥＰ[b]	0.2	0.2	0.3	—	0.1
	その他の配合剤 ポリエチレンワックス	1	5	—	4	2
	その他の配合剤 ジエチルジチオカルバミン酸亜鉛	0.1	0.1	—	0.1	0.1
	その他の配合剤 1,1-ジ(t-ブチルペルオキシ)-3,3,5-トリメチルシクロヘキサン	—	—	0.15	0.1	0.1
	その他の配合剤 γ－グリシドキシプロピルトリメトキシシラン	2	2	—	1.5	—
	その他の配合剤 四フッ化エチレン樹脂	—	—	10	—	—
	その他の配合剤 エチレンビスステアリン酸アミド	—	—	0.3	—	—
混練温度（℃）		220～250	210～240	220～240	200～240	220～250

(a)：堺化学工業（株）製　　(b)：旭電化（株）製

【００４６】

【表７】

		実施例６	実施例７	実施例８	実施例９	実施例10	厚生省告示規格値
厚生省告示項目	外観＊	99.3	99.3	99.5	99.5	99.3	無色透明
	pH	0.2	0.3	0.1	0.1	0.1	＋2.0 以下
	重金属(ppm)	0.1	0.1	0.02	0.03	0.03	1 ppm 以下
	$KMnO_4$還元性物質	0.2	0.3	0.1	0.1	0.2	2.0 mℓ以下
	蒸発残留物	0.3	0.2	0.1	0.1	0.1	1.0 mℓ以下

＊：光長 220～750nm の透過率で第12改正日本薬局方の試験法に準拠

【００４７】以上の本発明実施例では、ポリスルホン酸系樹脂として繰り返し単位がｒ、ｎ、ｗ、ｕ、ｆの樹脂のいずれか１種と、ＩＩＲ弾性体がＩＩＲ、ＢＩＩＲ，ＣＩＩＲ，ＤＶＩＩＲのいずれか各１種である組合せの例を示したが、本発明においてはポリスルホン系樹脂の１種以上全種のいずれか、およびＩＩＲの１種以上全種のいずれかの組合せも同様に有効である。具体的には前記した繰り返し単位がａ～ｗのうちの１種ないし全種の

ポリスルホン酸のうちのいずれかと、ＩＩＲ、ＢＩＩＲ，ＣＩＩＲ，ＤＶＩＩＲのうちの１種ないし全種のうちのいずれかとの組み合わせからなる。

【００４８】以下に本発明の実施態様を要約した形で示す。

（１）　イソブチレンーイソプレン共重合系弾性体の１種以上９５～５重量%とポリスルホン系樹脂の１種以上５～９５重量%とを含有してなるポリスルホン系樹脂組成物。

（２）　イソブチレンーイソプレン共重合系弾性体の１種以上１００重量部に対しポリスルホン系樹脂を５～４０重量部配合してなるポリスルホン系樹脂組成物からなる医療用，医薬品用器具栓体。

（３）　イソブチレンーイソプレン共重合系弾性体の１種以上１００重量部に対しポリスルホン系樹脂を５～３０重量部配合してなるポリスルホン系樹脂組成物からなる医療用，医薬品用器具栓体。

（４）　ポリスルホン系樹脂の１種以上１００重量部に対してイソブチレンーイソプレン共重合系弾性体の１種以上を２～１００重量部配合してなるポリスルホン系樹脂組成物からなる医療用，医薬品用器具。

（５）　ポリスルホン系樹脂の１種以上１００重量部に対してイソブチレンーイソプレン共重合系弾性体の１種以上を５～５０重量部配合してなるポリスルホン系樹脂組成物からなる医療用，医薬品用器具。

（６）　ＩＩＲと繰り返し単位が（－Ｐｈ－SO_2－Ｐｈ－Ｓ－）$_n$〔但しｎは１～２０００の整数を意味する〕で表されるポリスルホン樹脂とが配合されてなる上記（１）記載のポリスルホン系樹脂組成物。

（７）　ＢＩＩＲと繰り返し単位が（－Ｐｈ－SO_2－Ｐｈ－Ｏ－Ｐｈ－Ｃ（CH_3）（CH_3）－Ｐｈ－Ｏ－）$_n$〔但しｎは１～２０００の整数を意味する〕で表されるポリスルホン樹脂とが配合されてなる上記（１）記載のポリスルホン系樹脂組成物。

（８）　ＣＩＩＲと繰り返し単位が（－Ｐｈ－SO_2－Ｐｈ－Ｏ－）$_n$〔但しｎは１～２０００の整数を意味する〕で表されるポリスルホン樹脂とが配合されてなる上記（１）記載のポリスルホン系樹脂組成物。

（９）　ＢＩＩＲと繰り返し単位が（－Ｐｈ－SO_2－Ｐｈ－Ｏ－Ｐｈ－Ｐｈ－Ｏ－）$_n$〔但しｎは１～２０００の整数を意味する〕で表されるポリスルホン樹脂とが配合されてなる上記（１）記載のポリスルホン系樹脂組成物。

（１０）　ＣＩＩＲと繰り返し単位が（－（CH_3）Ｐｈ－SO_2－Ｐｈ（CH_3）（CH_3）－Ｏ－Ｐｈ－ＣＯ－Ｐｈ－Ｏ－）$_n$〔但しｎは１～２０００の整数を意味する〕で表されるポリスルホン樹脂とが配合されてなる上記（１）記載のポリスルホン系樹脂組成物。

（１１）　ＤＶＩＩＲ、繰り返し単位が〔－Ｐｈ－SO_2－Ｐｈ－Ｏ－Ｐｈ－Ｃ（CH_3）（CH_3）－Ｐｈ－Ｏ－）$_n$〔但しｎは１～２０００の整数を意味する〕で表されるポリスルホン樹脂及び繰り返し単位が（－Ｐｈ－SO_2－Ｐｈ－Ｏ－）$_n$〔但しｎは１～２０００の整数を意味する〕で表されるポリスルホン樹脂とが配合されてなる上記（１）記載のポリスルホン系樹脂組成物。

（１２）　ＤＶＩＩＲ、繰り返し単位が（－Ｐｈ－SO_2－Ｐｈ－Ｏ－）$_n$〔但しｎは１～２０００の整数を意味する〕で表されるポリスルホン樹脂及び繰り返し単位が（－Ｐｈ－SO_2－Ｐｈ－Ｏ－Ｐｈ－Ｐｈ－Ｏ－）$_n$〔但しｎは２～２０００の整数を意味する〕で表されるポリスルホン樹脂とが配合されてなる上記（１）記載のポリスルホン系樹脂組成物。

（１３）　ＤＶＩＩＲと繰り返し単位が（－Ｐｈ－SO_2－Ｐｈ－Ｏ－）$_n$〔但しｎは２～２０００の整数を意味する〕で表されるポリスルホン樹脂とが配合されてなる上記（１）記載のポリスルホン系樹脂組成物。

【発明の効果】本発明による医療用，医薬品用器具は、下記の効果を奏する。

１）日本薬局方の規格値に合格する高い衛生性を有する、

２）酸素透過バリヤ性を有する、

３）微粒子，ゴム破片の剥離，薬液漏れ，撥水性，注射針刺し抵抗，水蒸気透過量，ヘッドスペースのガス，耐アルカリ溶液性、吸水量，薬液の吸着に関して優れた衛生性を有する。

【図面の簡単な説明】

【図１】本発明に係る薬液用ゴム栓をガラス瓶に適用した一具体例を示す概略断面図である。

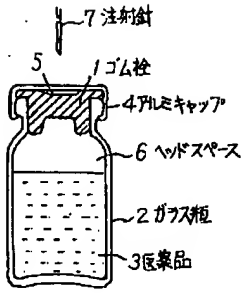
【図２】本発明に係る輸液用容器の断面図である。

【図３】本発明に係る注射器の断面図である。

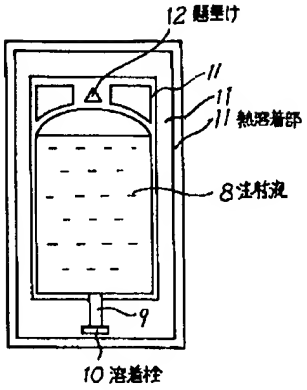
【符号の説明】

１　ゴム栓、　２　ガラス瓶、　３　医薬品、　４　アルミキュャップ、　５　針入部、　６　ヘッドスペース、　７　注射針、　８　注射液、　９　容器口部、　１０　溶着栓、　１１　熱溶着部、　１２　懸垂け、　１３　注射筒、　１４　滑栓、　１５　注射針、　１６　押子棒。

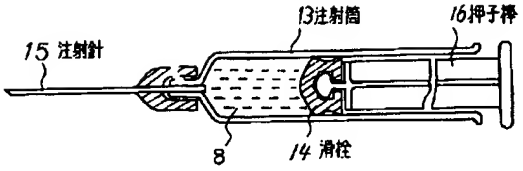
【図１】



【図２】



【図３】



フロントページの続き

(51) Int. Cl.[6]		識別記号	庁内整理番号	F I	技術表示箇所
C08L	9/00	LBM			
	81/06	LRF			
// A61M	5/178				

CLAIMS

[Claim(s)]
[Claim 1] The polysulfone system resin constituent which comes to contain an isobutylene-isoprene copolymerization system elastic body and polysulfone system resin.
[Claim 2] The polysulfone system resin constituent according to claim 1 which comes to contain 99 - 1% of the weight more than per sort of an isobutylene-isoprene copolymerization system elastic body, and 1 - 99% of the weight more than per sort of polysulfone system resin.
[Claim 3] The polysulfone system resin constituent according to claim 1 or 2 characterized by being the mixture or the alloy ghost of one or more sorts of an isobutylene-isoprene copolymerization system elastic body, and polysulfone system resin which comes to contain one or more sorts.
[Claim 4] Polysulfone system resin is n (-Ph-SO2-Ph-S-). It is the polysulfone system resin constituent according to claim 1 to 3 characterized by being what makes it a unit repeatedly [however, for n to mean the integer of 2-1000].
[Claim 5] Polysulfone system resin is n (-Ph-SO2-Ph-O-). It is the polysulfone system resin constituent according to claim 1 to 4 characterized by being what makes it a unit repeatedly [however, for n to mean the integer of 2-1000].
[Claim 6] The polysulfone system resin constituent according to claim 1 to 5 characterized by an isobutylene-isoprene copolymerization system elastic body containing isobutylene-isoprene copolymerization rubber, chlorination isobutylene-isoprene copolymerization rubber, bromination isobutylene-isoprene copolymerization rubber, or isobutylene-isoprene-divinylbenzene copolymerization rubber.
[Claim 7] the medical application which consists of a polysulfone system resin constituent which comes to contain an isobutylene-isoprene copolymerization system elastic body according to claim 1 to 6 and polysulfone system resin, and drugs -- an appliance -- an implement.
[Claim 8] medical application and drugs -- an appliance -- the medical application according to claim 7 characterized by an implement being a plug, and drugs -- an appliance -- an implement.
[Claim 9] medical application and drugs -- an appliance -- the medical application according to claim 7 characterized by an implement being a syringe, an infusion set, or a container, and drugs -- an appliance -- an implement.

DETAILED DESCRIPTION

[Detailed Description of the Invention]
[0001]
[Industrial Application] the medical application which health nature of this invention is high, for example, uses as instrument ingredients, such as a container, and consists of the suitable new polysulfone system resin constituent for a mothball and this constituent of those contents, and drugs -- an appliance -- it is related with an implement.
[0002]
[Description of the Prior Art] About medical application and the instrument for drugs, the class, the engine performance, quality, the trial item, the examining method, the value of standard, etc.

are set to the Pharmaceutical Affairs Law, a Japanese pharmacopoeia, and Notice of the Ministry of Health and Welfare. The product with which the iatrotechnique applied the various values of standard as a want matter to each item, an aforementioned approach, and an aforementioned numeric value further in the ever-advancing time is manufactured like today.

[0003] The transparent raw material used for medical application and drugs is mainly a glass product, and came as an instrument combining the Plastic solid which uses natural rubber as a raw material as an elasticity elastic body for being able to come, and it being alike, for example, sealing. however, recent years -- synthetic resin and synthetic rubber -- medical application and drugs -- an appliance -- it inquires as a raw material of an implement and marketing is also carried out.

[0004]

[Problem(s) to be Solved by the Invention] by the way, the medical application and drugs which are conventionally used widely -- an appliance -- there are the following properties and troubles about an implement raw material. Plasticizers, such as stabilizers, such as for example, a tin system added by resin, cadmium, and a zinc salt double salt compound, and dioctyl phthalate, dioctyl adipate, tricresyl phosphate, etc. should elute and pollute a polyvinyl chloride (abbreviated name PVC) in drugs and a drug solution. Environmental destruction may be caused when the resin product other than the PVC raw material monomer remaining in resin is discarded. The product with polyethylene (abbreviated name PE) made [with a product] from it because softening temperature is low serves as an instrument which cannot carry out high-pressure steam sterilization. Pasteurization is difficult although high-pressure steam sterilization can do polypropylene (abbreviated name PP). There is a report which denaturalized, made resin transparence and used it as medical-application raw material (JP,3-163144,A, said 3-28246 each number official report). Although PE and PP are comparatively excellent in the permeability-proof over moisture and humidity, gas cutoff nature, such as oxygen and carbon dioxide gas, is bad, and a content drug has the problem oxidized and discolored. As an approach of improving the fault of such PE and PP [whether ethylene and the saponification object (abbreviated name EVOH) of a vinyl acetate copolymerization component are mixed with PE and PP, and] or making it the package object which carried out the laminating to PE, PP, and EVOH is proposed (for example, "package film --) practical use thermal-resistance:plastics age of a shaping container and a bottle No. 6 (1992) "high barrier multilayer plastic envelope: Pharmaceutical factory vol.6, No.12 (1986)", "The gas barrier nature container of plastics, the gas barrier nature of plastics, and container shaping approach:hood packaging vol.32-No.3", "high gas barrier nature wrapping : Plastics vol.38, No.5" (1987), The application and the actual condition to "barrier nature resin container : Plastics vol.27, No.5" (1977), "barrier nature composite material and PVDC : KOMPA tech vol.15, No.1" (1987), Barrier resin which functionalizes "packing material : KOMPA tech vol.17, No.6(1989)", The "latest functional wrapping : Industrial ingredient vol.37, No.14(1989)", The trend of the "latest functional container: Since water absorption and hygroscopicity of EVOH are very strong, when humidity and moisture live [science, industrial vol.61-4 (1987)", etc.] together at the time of high-pressure steam sterilization etc., it has the fault that gas electric shielding validity, such as oxygen and air, is very weak. Although a glass raw material is a raw material excellent in a heatproof, an acid-proof history, transparency, etc., there is a trouble that the alkali generated from a glass front face and the particle which exfoliates from glass pollute a chemical and a drug solution. There are problems, such as an offensive odor and formaldehyde generating, from the resin of polyphenylene ether resin (abbreviated name PFE), polyethylene terephthalate (abbreviated name PET), polybutylene

terephthalate (abbreviated name PBT), and a polycarbonate (abbreviated name PC). In case natural rubber (abbreviated name NR) and the polyisoprene rubber (abbreviated name IR) of synthetic rubber, butadiene rubber (abbreviated name BR), styrene butadiene rubber (abbreviated name SBR), nitrile rubber (abbreviated name NBR), isobutylene isoprene rubber (abbreviated name IIR), halogenation isobutylene isoprene rubber (BIIR, CIIR), etc. are used for medical application and drugs, they have the trouble that the vulcanizing agent, vulcanization accelerator, and reinforcing agent which vulcanize rubber cause elution, exfoliation, etc., and pollute a chemical and a drug solution. this invention persons have proposed the rubber goods (JP,5-43740,B) which already blended the polyethylene of ultrahigh molecular weight with IR, BR, and SBR, and the rubber goods (JP,4-213347,A) which combined the special vulcanizing agent with IIR. the medical application and drugs using the new raw material with which this invention canceled the fault of elegance conventionally -- an appliance -- the medical application which consists of the new polysulfone system resin constituent and new it which especially health nature is high, it uses for instruments, such as a container, and there are no pollutant elution, exfoliation, etc. to contents for the purpose of offer of an implement, and were suitable for the mothball of contents, and drugs -- an appliance -- it has the intention of an implement.

[0005]

[Means for Solving the Problem] This invention offers the polysulfone system resin constituent which comes to contain an isobutylene-isoprene copolymerization system elastic body and polysulfone system resin as The means for solving a technical problem. As a desirable mode in this invention, the polysulfone system resin constituent which is the mixture or the alloy ghost of one or more sorts of an isobutylene-isoprene copolymerization system elastic body and polysulfone system resin which comes to contain one or more sorts is mentioned especially. moreover -- as the especially desirable mode in this invention -- this polysulfone system resin -- n (-Ph-SO2-Ph-S-) The thing which makes it a unit repeatedly [however, for n to mean the integer of 2-1000], or (-Ph-SO2-Ph-0-) n what makes it a unit repeatedly [however, for n to mean the integer of 2-1000] -- it comes out and a certain thing is mentioned. the medical application which consists of a polysulfone system resin constituent with which this invention comes to contain the isobutylene-isoprene copolymerization system elastic body and polysulfone system resin of this invention further described above, and drugs -- an appliance -- an implement is offered. A plug is especially mentioned as a desirable mode of the medical application of this invention, and the instrument for drugs. furthermore, the medical application of this invention and drugs -- an appliance -- it is also an especially desirable mode that an implement is a syringe, an infusion set, or a container.

[0006]

[Function] The isobutylene-isoprene copolymerization system elastic body (it may abbreviate to an IIR elastic body hereafter) concerning this invention Isobutylene-isoprene copolymerization rubber (IIR), the rubber which made chlorine react to isobutylene-isoprene copolymerization rubber (CIIR), The rubber which made the bromine react to isobutylene-isoprene copolymerization rubber (BIIR), It is the generic name of isobutylene-isoprene-divinylbenzene copolymerization rubber (abbreviated name DVIIR). It is the elastic body which comes to vulcanize IIR, CIIR, BIIR, and DVIIR using one or more sorts chosen from a vulcanizing agent, for example, sulfur, a zinc white, magnesium, an amine compound, organic peroxide, a MAIMIDO compound, etc.

[0007] the IIR elastic body concerning this invention -- 4.5 or less % of the weight of isoprene radical contents, and average molecular weight 10,000-650,000 For example, the 100 weight

sections of IIR are received. it is -- Sulfur, for example, t-butylperoxy isopropyl, n-butyl -4, 4'-screw (t-butyl peroxide) valerate, Organic peroxide, such as 1 and 1-JI (t-butylperoxy) 3 and 3 and a 5-trimethyl cyclohexane, For example, maleimide, such as N and N'-m-phenylene bismaleimide A vulcanizing agent and dipentamethylenethiuramtetrasulfide, such as a zinc white, It can manufacture with the well-known means of vulcanizing vulcanization accelerators, such as zinc diethyldithiocarbamate, tetramethylthiurammonosulfide, and tetramethylthiuramdisulfide, 0.5 - 2 weight section, in addition by carrying out heating application of pressure, for example.

[0008] The elastic body of BIIR and CIIR concerning this invention can be manufactured by carrying out 1-5 weight section addition, and heating and pressurizing vulcanizing agents, such as a zinc white and magnesium oxide, for example, the organic amine compound which has an amino group and a carboxyl group in intramolecular, the same vulcanization accelerator as the case of said IIR elastic body, etc. to the 100 weight sections of BIIR and CIIR.

[0009] The elastic body of DVIIR concerning this invention can be manufactured by carrying out 0.5-2 weight section combination, heating and pressurizing the same organic peroxide as the elastic body of IIR, and a case, and vulcanizing it to the DVIIR100 weight section.

[0010] As preparation of vulcanization of the elastic body concerning this invention, and the resin constituent of this invention, and the concrete technique of shaping from this constituent After mixing the various above compounding agents beforehand to crude rubber, it pressurizes at 160-220 degrees C with an internal mixer or a mixed extruding machine. After performing dynamic vulcanization to heat, it can mix to polysulfone resin or mixing, the approach of alloy-izing, or the approach of blending the vulcanization accelerator other than a vulcanizing agent, blending a polysulfone acid further, and carrying out shaping vulcanization within metal mold can be adopted.

[0011] The polysulfone system resin concerning this invention is resin of the super-macromolecule object which used association with an aromatic series system hydrocarbon group and a sulfonyl group (-SO2-) as the principal component. A phenyl group and a phenylene group are mentioned as this aromatic hydrocarbon radical. The phenyl group or phenylene group combined with one sulfonyl group has one case and 2-7 things, and when it is the latter, they is a biphenyl radical, a bis-phenyl alkane radical, a triphenyl radical, etc. Moreover, the polysulfone system resin of this invention can have low-grade alkyl groups other than a phenyl group, a phenylene group, or a sulfonyl group, such as an oxy-radical (-O-), a thio radical (-S-), a carbonyl group (-CO-), and a methyl group, as a constituent.

[0012] The example of the repeat unit of the polysulfone system resin concerning this invention is given to below. In the following example a-w, a code means as follows. Ph: -- phenyl group or phenylene group, and -SO2-: -- a sulfonyl group, a -O-:oxy-radical, a -S-:thio radical, a -CO-:carbonyl group, and a CH3-:methyl group. n: Integer a of 2-1000 : () [-Ph-SO2] -) -- nb:(-Ph-SO2-Ph-) nc:(-Ph-SO2-Ph-Ph-SO2-Ph) nd:(-Ph-SO2-Ph-Ph-Ph-SO2-Ph) ne: () [-Ph-SO2-Ph-Ph-Ph-SO2] -) -- nf:(-Ph-SO2-Ph-O-) ng:(-Ph-SO2-Ph-SO2-Ph-O-) nh:(-Ph-SO2-Ph-SO2-Ph-O-Ph-O-) ni: () [-Ph-SO2-Ph-PhSO2] - Ph-O-nj:(-Ph-SO2-Ph-Ph-SO2-Ph-O-Ph-O-) nk:(-Ph-SO2-Ph-Ph-SO2-Ph-O-Ph-Ph-O-) nl:(-Ph-SO2-Ph-Ph-O-Ph-O-) nm : () [-Ph-SO2] - Ph-O-Ph-O-Ph-O-nn:(-Ph-SO2-Ph-O-Ph-Ph-O-) no:(-Ph-SO2-Ph-CH2-Ph-SO2-Ph-O-) np:[-Ph-SO2-Ph-Ph-O-Ph-C () [CH3] -Ph-O-]nq:[-Ph-SO2 (CH3) - Ph-O-Ph-C(Ph) (Ph)-Ph-O-]nr:(-Ph-SO2-Ph-S-) ns:(-Ph-SO2-Ph-O-Ph-CO-Ph-O -) nt:(-Ph-SO2-Ph-O-Ph-O-) nu:[-Ph-SO2 - Ph-O-Ph-C (CH3) () [CH3] -Ph-O-:[ ]nv:(-Ph-Ph-SO2-Ph-Ph-SO2-Ph-O-) nw] [-(CH3) (CH3)-Ph-SO2-Ph(CH3) (CH3)-O-Ph-CO-Ph-O-] n [0013] The polysulfone system resin concerning this invention is a

polymer which uses as a principal component a repeat unit which was described above. A conventionally well-known technique, for example, JP,45-21318,B -- said -- 46-21458 -- said -- 47-617 -- said -- 53-25879 -- said -- 56-2091 -- said -- 61-12930 and JP,52-96700,A -- said -- 53-10696 -- said -- 59-12930 -- said -- 63-21030 -- said -- 63-243128 -- JP,1-315422,A -- said -- 1-318040 -- said -- 3-41120 -- said -- 3-95200 -- said -- a polymerization is carried out with the technique indicated by 4-335030, said 5-9453 each number official report, etc., and it can manufacture. average molecular weight of this polysulfone system resin 5,000-950,000 it is -- many carrying-out [using an alkaline catalyst]-in polar organic solvent-polymerization of this resin approaches are adopted. However, as for the polysulfone system resin used for this invention, what repeated solvent washing, warm water washing, etc. and removed a raw material compound, the oligomer of low molecular weight, an inorganic compound (many are NaCl), etc. as much as possible is desirable. Various kinds of well-known techniques are applicable to the purification means of such this polysulfone system resin. It is tough nature, high intensity, thermal resistance, KUREBU-proof nature, and abrasion resistance, and the polysulfone acid system resin concerning this invention is resin of a frank color and transparency, it has the resistance excellent also in an acid, alkali, and salting in liquid, and can also bear the high temperature service in the inside of a detergent and a hydrocarbon. furthermore -- since it has the property that it can be repeatedly equal also to 130 degrees C and the autoclave sterilization for 30 minutes with steam-proof and hot water resistance -- medical application and drugs -- an appliance -- it uses for an implement and is dramatically advantageous.

[0014] In addition, what added the stabilizer of the amount of macromolecules comparatively as polysulfone acid resin of this invention is desirable. As such a stabilizer, for example Tetrakis [methylene (3, 5-G t-butyl-4-hydroxyphenyl) propionate] methane:trade name IRUGA NOx 1010 (Ciba-Geigy make), Triethylene glycol-bis--3-(2-t-butyl-4-hydroxy-5-methylphenyl) propionate : Trade name IRUGA NOx 245 (Ciba-Geigy make), Screw (2, 6-G t-butyl-4-methylphenyl) PENTA ERIS toll diphosphite : Trade name ADEO stub PEP-36 (product made from Asahi Electrification), It is desirable for N and N'-m-phenylene bismaleimide, a tocopherol, etc. to be mentioned and to carry out 0.01-0.5 weight section addition of these one or more kinds to this polysulfone acid resin 100 weight section.

[0015] The constituent of this invention comes to contain the above-mentioned IIR elastic body and polysulfone system resin. Moreover, this IIR elastic body and polysulfone system resin can also blend one or more sorts respectively. Polysulfone acid system resin is preferably blended in 95 - 5% of the weight of the range 99 to 1% of the weight to an IIR elastic body. this blending ratio of coal -- medical application and drugs -- an appliance -- it is desirable to choose corresponding to the class of implement and the hard and soft degree suitable for that instrument. For example, when applying as an instrument plug for medical application and drugs, it is desirable to carry out 5-40 weight section combination of the polysulfone acid system resin to the IIR elastic body 100 weight section. It is 5 - 30 weight section especially preferably. This is because the physical characteristic as a plug, for example, the physical characteristic needed in the case of injection needling, will be lacked under in 5 weight sections when it cannot acquire to the desired end, suitable property, for example, elasticity, but 40 weight sections are exceeded. moreover, medical application and drugs -- an appliance -- the elastic body chosen from BIIR, CIIR, and DVIIR to the polysulfone acid 100 weight section when using it for the body of a container of an implement etc. -- the 2 - 100 weight section -- desirable -- 5 - 50 weight section -- mixing -- or it alloy-izes. the resin object of thermal resistance and high elasticity -- becoming -- a medical-application instrument and drugs -- an appliance -- as an implement, thermal resistance

is high, therefore serves as the container and instrument which repeat heat sterilization, high voltage auto KUREBU sterilization, and ethyleneoxide sterilization, and can perform them. Therefore, it fabricates and is suitable for the instrument for an operation, a syringe, a syringe-cum-a container, etc. Moreover, it could be made the film, and could use for raw materials, such as bags for infusion solutions, and it became clear that it could use suitable for the preservation container of the high TARORI transfusions containing grape sugar and amino acid etc. In this film shaping, it is desirable to mix processing aid, a graft copolymer, etc. to the constituent of this invention.

[0016] The constituent which consists of the IIR elastic body and polysulfone resin of this invention as mentioned above may be mixture, and can also be made into an alloy ghost. Moreover, processing aid can be added in order to make the workability of mixture and an alloy ghost, and a moldability good. As such processing aid, for example Higher-fatty-acids:, for example, arachin acid, Metal soap:, for example, zinc stearate, calcium stearates, such as behenic acid, Fatty-acid amides:, for example, styrene bis-stearyl amides, such as an aluminum stearate salt, Ethylene bis-oleic amide, a behenic acid amide, octadecanamide, etc., Higher-fatty-acid ester:, for example, long-chain-fatty-acid ester of 20-24 carbon numbers, Wax:, for example, a micro crystallin wax, such as a sorbitan fatty acid ester The amount polyethylene of giant molecules, alcohols of 16-18 carbon numbers, such as polyethylene wax, One or more kinds, such as silicone oils, below 10 weight sections, a graft copolymer, a block copolymer (for example, the hydrogenation object of a styrene-butadiene-rubber-block copolymer and this copolymer --) A poly dimethylsiloxane-polyethylene oxide block copolymer, an ethylene-glycidyl methacrylate graft copolymer etc. -- etc. -- from -- by blending one or more kinds chosen below 20 weight sections, it can consider as a very uniform alloy ghost, and workability can be improved.

[0017] As a means to mix and knead the IIR elastic body and polysulfone system resin concerning this invention, and to alloy-ize them, conventionally, using well-known equipment, for example, an internal mixer, one shaft, or a twin screw extruder, it can carry out at the temperature of 120-380 degrees C, and becomes uniform mixture and an alloy ghost. moreover -- as it is -- extrusion molding -- carrying out -- medical application and drugs -- an appliance -- it can also consider as an implement. the medical application concerning this invention, and drugs -- an appliance -- the product fabricated as an implement -- each -- 48. test for rubber closure for aqueous infusions of a Japanese pharmacopoeia (the 12th amendment), the plastic envelope examining method for 49. infusion solutions, and Notice of the Ministry of Health and Welfare No. 301 -- said -- No. 413 -- said -- the medical application which suits No. 442, and drugs -- an appliance -- it is an implement and can consider as a syringe, a syringe-cum-a container, and an infusion set instrument. Moreover, it becomes drugs and the container which has the outstanding description that the quality can be held for a content chemical over a long period of time as a container of a drug solution.

[0018]

[Example] Hereafter, although an example explains this invention to a detail, this invention is not limited to these.

[Polymerization:1 which is the Pol sulfonic acid] NaHS(47 % of the weight of concentration) 358g, NaOH(48 % of the weight of concentration) 225g, CH3 COONa123g, Na2 CO3 19g, and N-methyl pyrrolidone 2376g are taught to a 10,000ml autoclave, and it agitates at the temperature of 130 degrees C for 3 hours, passing nitrogen gas. After cooling the mixture at 70 degrees C, it mixes agitating N-methyl pyrrolidones 297g and 4 and 4-dichloro diphenylsulfone

878.5g mixture in this reactant, it heats at the temperature of 260 degrees C for 4 hours, and a polymerization is performed. next -- while cooling agitating to 120 degrees C with 1-degree-C speed for /and agitating in 9g [of acetic acids], and N-methyl pyrrolidone 2583g -- gradual -- slushing -- a polymer -- a particle -- after making it deposit as powdered and carrying out a ** exception -- 1500ml of 70-degree C warm water -- washing -- it washes in methanol 1000ml further. It is IRUGA NOx 1010 to the obtained polymer 100 weight section. It dries in a vacuum after adding the 0.1 weight sections. It was the amount of resin of 632g and glass transition temperature of 192 degrees C which were obtained. The repeat unit of this resin was n (-Ph-SO2-Ph-S-) r, i.e., the above mentioned repeat unit, in light yellow transparence. This resin is abbreviated to Resin r.

[0019] The [examples 1-3 and the example 1 of a comparison, and 2] IIR[trade name The 2.0-mol % and ML1+8 100 ** 42]100 weight section is received whenever [JSR Butyl 365, Japan Synthetic Rubber Co., Ltd. make, and partial saturation]. the ratio (the section in a table means the weight section) which shows polysulfone resin r obtained above in the following table 1 -- blending -- an internal mixer and a twin screw extruder -- kneading -- 2 rolls -- ****(ing) -- combination -- the ground was created.

[0020]

[A table 1]

[0021] ** of the above-mentioned table 1 - ** are as follows.

** PE : low density polyethylene, show REXX M222, the Showa Denko K.K. make, 92 degrees C of softening temperatures.

** Bulking agent : trade name Whitetex:Southern Product made from Clay.

** 2, the 5-dimethyl -2, 5-JI (t-butylperoxy) hexane.

** N and N'-m-phenylene bismaleimide.

** Micro crystallin wax (melting point of 110 degrees F, NIPPON SEIRO CO., LTD. make).

** gamma-mercaptotrimethoxysilane : Nippon Unicar make A-189 (trade name).

[0022] the combination obtained above -- the ground with an oscillating disk rheometer (O. it being called R.R. for short) testing machine Society of Rubber Industry, Japan -- VOL.40 (1967) -- p874 and ASTM D-2705 and SRIS 3102 A minute angle oscillation (torsional oscillation) of an oscillating-type vulcanization trial [revolution reciprocating motion is given. the -- corresponding -- stress -- torque value -- ****** -- measuring -- torque -- a peak price -- (-- c --) -- asking -- this -- torque -- the minimum value -- (-- b --) -- a difference -- asking --] -- carrying out -- the result -- a table 2 -- collecting -- being shown .

[0023]
[A table 2]

[0024] Since an example 1 has the difference of torque value [(c)-(b)] larger than the ground of the example 1 of a comparison, and the example 2 of a comparison and hardness is also large as shown in a table 2, it turns out that rubber is a high elasticity object. Moreover, in the example 2 which increased the quantity of Resin A, and the example 3 which added the silane coupling agent, the addition effectiveness shows torque value higher than an example 1 and Hs value, respectively.
[0025] next, it obtained above -- each -- the rubber stopper for drugs shown in drawing 1 was fabricated by the vulcanization condition:temperature of 170 degrees C, and : during 10 minutes using the ground. In addition, a carboy 2 is capped with a rubber stopper 1, the condition that the aluminium cap 4 wound and fastened is shown, in 3, drawing 1 is the outline sectional view of one example which applied this rubber stopper to the carboy, and, as for drugs and 5, 7 shows [needle admission into a club and 6 show a head space, and] a hypodermic needle. The special health trial which the examining methods and this invention persons of the 12th amendment Japanese pharmacopoeia are using about each rubber stopper was performed. The result is shown in a table 3 and a table 4. A special health trial is performed as follows.
[0026] The other special amounts of health trial particles (trial of the particle weight generated from a rubber stopper); ten rubber stoppers are put in into a hard-glass bottle, it vibrates on a package with a film and 300ml of non-**** and container opening are vibrated for 20 seconds with 2 revolutions-per-second extent by hand. After putting after that for 1 hour, the number of an underwater particle is measured with an optical electric shielding mold automatic particle measuring instrument (product made from HIAC). In addition, since existence of the particle 5 micrometers or more in a parenteral solution causes the problem of blockading a blood vessel, it serves as a critical item.
[0027] Exfoliation of a rubber fragment (Fragmentation); 5ml of water is put into the bottle (10ml capacity) of the configuration shown in drawing 1 as 2, a rubber stopper 1 is capped, and then an aluminium cap 4 is rolled and fastened. 2ml water is put into the glass syringe which attached the trial needle [22G (0.70x32mm)], and the needle admission into a club 5 of a rubber stopper is made to penetrate this 20 times. A hypodermic needle is drawn out after pouring in the water in a glass syringe into a bottle at the time of the 20th penetration. After vibrating the inside

of a bottle, a rubber stopper is removed, content liquid is filtered and the rubber piece number on a filter paper is counted. Although an exam method is what improved the approach of the British standard 3263 (it abbreviates to BS) and the specification of BS is three or less rubber pieces, less than two pieces are demanded in this current this industry.

[0028] Drug solution leakage; 500ml of water is put into the bottle 2 of drawing 1 , a rubber stopper 1 is capped, and an aluminium cap 4 is rolled and fastened. Leave it for 1 hour, running through with the rocket needle 7 (the JMS nature No. 200, rocket needle with an infusion set) from the needle admission into a club 5 of the rubber stopper after heating this for 30 minutes at 121 degrees C within a container, and maintaining a bottle at a handstand condition, then stab with a vent wire, 400ml of water in a bottle is made to flow out, the liquid spill at drawing and this time (ml) is observed for the rocket needle from a rubber stopper at this event, and it measures.

[0029] Water repellence (Water repellency); 500ml of distilled water is put into the bottle 2 of drawing 1 , a rubber stopper 1 is capped, and an aluminium cap 4 is rolled and fastened. Next, a bottle wall is observed, after putting into a proof-pressure heating container, steaming for 30 minutes at the temperature of 121 degrees C and leaving it in a room temperature for 24 hours. What does not accept waterdrop at this time is considered as acceptance.

[0030] Injection needling resistance-force trial (Determination of penetrability); the force in case a hypodermic needle 7 (21. the S.W.G. outer diameter of 0.81mm, die length of 38mm) penetrates a rubber stopper the rate for 20cm/is measured with a measurement machine (tension form spreading tension testing machine), and it considers as acceptance by 0.5 kg. An exam is amelioration of the trial to which BS is equivalent. BS value of standard passes by 1000g or less.

[0031] 8ml of brine solutions is put in 2% of the weight into the carboy of the steam permeability test chart 1 , a rubber stopper 1 is capped, and an aluminium cap 4 is rolled and fastened further. Change of weight is measured after preservation for six months at a room temperature in the desiccator into which silica gel was put for this glass bottle, and the amount of steam transparency of a rubber stopper (g) is measured. The five averages are taken and 1g or less is considered as acceptance. It is this invention persons' independence specification testing.

[0032] 8ml of brine solutions is put in 2% of the weight into the carboy 2 of gas-constituents trial drawing 1 in a head space, a rubber stopper 1 is capped, and an aluminium cap 4 is rolled and fastened further. It is left for about 10 hours, after carrying out steamy heating of this carboy for 60 minutes at the temperature of 121**1 degree C with a proof-pressure container. Next, gas 5ml of the head space 6 in a bottle is extracted in the syringe for gas, and this is measured in gas chromatography. Column: See the existence of the peak of a part for 101 (180-200 mesh WHP) and carrier gas helium50ml/, and 10%OV-temperature [column / of 100-200 degrees C (4 degree-C temperature up / A part for //)] **, and size. An exam is a trial which investigates the ultralow volume generation of gas by the rubber and the compounding agent which have been a problem in recent years.

[0033] Alkali-proof solution trial; ten rubber stoppers are put into an alkali-proof container, and it is sodium carbonate 0.5 of the amount of 10 times of rubber stopper weight. After adding a weight % solution, this rubber stopper is capped, and an aluminium cap is rolled and fastened. Next, steamy heating is carried out for 30 minutes at the temperature of 121 degrees C with a high pressure vessel. Except for the rubber stopper after neglect and cooling, the wavelength of 430nm and the permeability of a 650nm visible region are measured for test fluid in a quartz cell to a room temperature. 95% or more is considered as acceptance. the fundamental trial whose exam examines the relation between rubber and a drug solution -- the rubber goods with low

permeability -- adoption -- it is unsuitable.
[0034] Water absorption test; the rubber goods which carried out bridge formation shaping are dried by temperature the ordinary pressure of 105 degrees C for 3 hours. Next, it is the weight (A) after about 1-hour neglect in the desiccator containing a desiccating agent. It weighs precisely. Next, it dips into the purified water of the amount of 10 times of this rubber stopper, and steamy heating is carried out for 30 minutes the temperature of 121**1 degree C within a proof-pressure container as it is. After cooling, only a rubber stopper is left for 30 minutes in a desiccator, surface water is taken, and it is the weight at that time (B). It weighs precisely, and asks for (([(B)-(A)/(A)] x100) %), and 2 or less % of the weight is considered as acceptance.
[0035] The adsorption test of a drug solution; nitric-acid iso SORUBITO (the medicine for ischemic heart disease, the melting point of 72 degrees C, product made from Japanese-made medicine) was diluted with the physiological saline, and as 0.040 % of the weight, 3ml of this liquid was put into the 10ml bottle 2 at accuracy, the rubber stopper was capped, the aluminium cap was rolled, and it was left in the state of the handstand in total for 24 hours. This is applied to a high-speed liquid chromatograph (product made from HLPC), the amount of nitric-acid iso SORUBITO is measured and the loss in quantity which adsorbed is obtained. Column: FINEPAK SILC18 (a trade name, Jasco make), a mobile-phase methanol: Water = 7:3 and 1ml [of the rates of flow] a part for /, detector UVIDEC100-IV (a trade name, the Jasco make, 220nm)
[0036]
[A table 3]

[0037]
[A table 4]

[0038] As shown in a table 3 and a table 4, all this invention articles conform to the value of standard of the 12th amendment Japanese pharmacopoeia. In addition to it, it turns out that they are the container which can respond to the newest drugs, and the outstanding rubber stopper which can also suit the special independence trial item as an instrument. On the other hand, the product of the examples 1 and 2 of a comparison shows the result which poses a problem in several items, such as pH, a residue on evaporation, and the amount of particles.
[0039] [Example 4] The BIIR(product [made from EXXON CHEMICAL], ML1+8 125 degree-C 50, 0.6 % of the weight of bromine contents) 100 weight section, 1.0 weight sections [made from an active white (Sakai Chemical Industry stock)], N, and N'-m-phenylene bismaleimide (Kawaguchi Chemical Industry Co., Ltd. make) 2.0 weight section, insoluble sulfur (after mixing the 0.2 weight section made from Japanese Dry distillation with an internal mixer, kneading was performed for 7 minutes at the temperature of 160 degrees C, and it considered as dynamic vulcanizate.) the polysulfone resin (it POLYSULFONE(s) trade name UDEL [ ] --) refined independently the Union Carbide repeat unit -- said u:[-Ph-SO2-Ph-O-Ph-C(CH3) (CH3)-Ph-O-] n N-methyl pyrrolidone : The thing]100 weight section washed twice with the solvent which comes to heat water =1:0.5, The ethylene bis-octadecanamide (Nippon Kasei Chemical Co., Ltd. make) 1 weight section, It is the maleic-anhydride 5 weight section about a styrene-butadiene-ethylene copolymer. The block-copolymer (prototype) 5 weight section was made into the alloy ghost at the temperature of 160-220 degrees C with the internal mixer and the 2 ream type extruder. Next, it considered as the uniform film plate through T Thailand. 0.4mm in thickness JIS the place which are the tensile strength of 213kg/cm2, and 210% of elongation, and measured the amount of oxygen gas transparency as a result of measuring a physical property based on K6301 (product made from Yanamoto factory GTR) -- the temperature of 20 degrees C, and dryness -- 100cc[/m] 2 and 24 hrs/atm it was . the amount of oxygen gas transparency of the film plate which BIIR before kneading vulcanized -- 300 cc/m2 and 24 hrs/atm it was -- according to this invention, by mixing polysulfone resin with an IIR elastic body shows from

things that the gas barrier nature to oxygen was improved. In addition, the trial based on the plastic envelope examining method for 49. infusion solutions of the 12th amendment Japanese pharmacopoeia about the alloy ghost of BIIR of this invention and polysulfone acid resin is performed, and the result is shown in the after-mentioned table 5.
[0040] [Example 5] After mixing the CIIR(JSR CHLOROBUTYL 1068, trade name, Japan Synthetic Rubber Co., Ltd. make, ML1+8 125 degree-C 50, 1.2 % of the weight of halogen contents) 100 weight section, the active white (Sakai Chemical Industry Co., Ltd. make) 1.0 weight section, and the zinc-diethyldithiocarbamate 1.0 weight section with an internal mixer, kneading was performed for 7 minutes at the temperature of 160 degrees C, and it considered as dynamic vulcanizate. Polysulfone acid [trade name VICTREX PES, the product made from ICI which were refined independently, A repeat unit is said f:(-Ph-SO2-Ph-O-) n. A thing tetrahydrofuran: -- water: -- the thing]400 weight section further washed with the acetone after washing with the solvent which acetic-acid =20:5:0.1 heated -- The styrene-ethylene-styrene block-copolymer (Shilu chemical company treatment article) 10 weight section, The polyethylene terephthalate (polyethylene terephthalate [by Kuraray Co., Ltd.], grade KS700) 30 weight section was made into the alloy ghost at the temperature of 160-220 degrees C with the internal mixer and the 2 ream type extruder. Next, it considered as the uniform film plate with a thickness of 0.4mm through T Thailand. this film -- JIS physical based on K6301 -- the place which are the tensile strength of 256kg/cm2, and 180% of elongation, and measured the amount of oxygen gas transparency like the example 4 as a result of measuring a characteristic -- 85 cc/m2 and 24 hrs/atm it was . The created transfusions container is shown in drawing 2 . In drawing 2 , in the container regio oralis and 10, a joining plug and 11 express a heat welding and 12 expresses [8 / a parenteral solution and 9] ******. In addition, the trial based on the plastic envelope examining method for 49. infusion solutions of the 12th amendment Japanese pharmacopoeia is performed, and the result is united and shown in the after-mentioned table 5. As shown in a table 5, the product by this invention has passed the value of standard of the 12th amendment Japanese pharmacopoeia.
[0041]
[A table 5]

[0042] [Polymerization:2 which is a polysulfone acid] It is a screw (3, 5-dimethyl-4-hydroxyphenyl) sulfone to a 3000ml three necked flask. 306g (one mol), Chlorobenzene 1000ml and sulfolane 450ml are added and stirred. To the bottom of nitrogen-gas-atmosphere mind, heat at 60 degrees C and 250.5g of NaOH (45 % of the weight) solutions is added gradually. 50ml purified water is added, if heating is continued to the temperature of 120-140 degrees C and a reactant amounts to 145 degrees C except for chlorobenzene with azeotropy, it will cool at 130 degrees C, and it is a screw (4-fluoro phenyl) ketone. 218g is added and it reacts at 200 degrees C for 8 hours. It cooled, and the polymerization reaction object filled the bottom of stirring with a lot of methanols, deposited resin, was filtered, and washed and carried out the vacuum drying with an acetone and warm water. The amount of resin of 450g Repeat unit w:[-(CH3) (CH3) Ph-SO2-Ph(CH3) (CH3)-O-Ph-CO-Ph-O-] n, glass transition temperature of 240 degrees C. This resin is abbreviated to Resin w.

[0043] [Polymerization:3 which is a polysulfone acid] 4 and 4'-diphenolg [149] and 4 and 4'-dichloro diphenylsulfone 234g, 121.6g [of anhydrous potassium carbonate], N, and N'-dimethylacetamide 1200g is taught to a 4000ml three necked flask, the inside of a reactor is made into nitrogen-gas-atmosphere mind, is boiled, and N and N'-dimethylacetamide and water are made to flow out. After performing a polymerization reaction for about 4 hours, it cools, potassium carbonate is carried out a ** exception, the bottom of stirring is filled with a lot of methanols, a resin object is deposited, a methanol and warm water wash, and a vacuum drying is performed. The obtained amount of resin is 340g. Glass transition temperature of 220 degrees C. this resin -- a repeat unit -- said n:(-Ph-SO2-Ph-O-Ph-Ph-O-) n it is -- this resin is abbreviated to Resin n.

[0044] [Examples 6-10] It blended with the ratio (weight section) shown in a table 6 about various kinds of polysulfone resin and IIR elastic bodies. After mixing with each raw material powder beforehand, it fabricated in the glass syringe configuration shown in drawing 3 after dynamic vulcanization at the extruder temperature of 180-220 degrees C. In drawing 3 , in a glass syringe and 14, **** and 15 express a hypodermic needle and 16 expresses [13] ******.

Based on Notice of the Ministry of Health and Welfare No. 442, it examined about the obtained glass syringe. A result is shown in a table 7.
[0045]
[A table 6]

[0046]
[A table 7]

[0047] As polysulfone acid system resin, in this invention, the combination of either of the one or more sort all kinds of polysulfone system resin and either of the one or more sort all kinds of

IIR has [any one sort and the IIR elastic body of the resin of r, n, w, u, and f] similarly it. [repeatedly effective in the above this invention example, although the unit showed the example of the combination which is IIR, BIIR, CIIR, or one sort of DVIIR each] It consists of combination with either of one sort thru/or all the kinds of either of the polysulfone acids of the one sort a unit is [sort] among a-w thru/or all the kinds specifically described above, IIR and BIIR, CIIR, and the DVIIR(s) repeatedly.

[0048] It is shown in the form where the embodiment of this invention was summarized, below.

(1) The polysulfone system resin constituent which comes to contain 95 - 5% of the weight more than per sort of an isobutylene-isoprene copolymerization system elastic body, and 5 - 95% of the weight more than per sort of polysulfone system resin.

(2) the medical application which consists of a polysulfone system resin constituent which comes to carry out 5-40 weight section combination of the polysulfone system resin to the one or more sort 100 weight section of an isobutylene-isoprene copolymerization system elastic body, and drugs -- an appliance -- an implement plug.

(3) the medical application which consists of a polysulfone system resin constituent which comes to carry out 5-30 weight section combination of the polysulfone system resin to the one or more sort 100 weight section of an isobutylene-isoprene copolymerization system elastic body, and drugs -- an appliance -- an implement plug.

(4) the medical application which consists of a polysulfone system resin constituent which comes to carry out 2-100 weight section combination of the one or more sorts of an isobutylene-isoprene copolymerization system elastic body to the one or more sort 100 weight section of polysulfone system resin, and drugs -- an appliance -- an implement.

(5) the medical application which consists of a polysulfone system resin constituent which comes to carry out 5-50 weight section combination of the one or more sorts of an isobutylene-isoprene copolymerization system elastic body to the one or more sort 100 weight section of polysulfone system resin, and drugs -- an appliance -- an implement.

(6) Repeat with IIR and a unit is n (-Ph-SO2-Ph-S-). It is the polysulfone system resin constituent of the above-mentioned (1) publication with which it comes to blend the polysulfone resin expressed with [however, n means the integer of 1-2000].

(7) A unit (polysulfone system resin constituent given in -Ph-SO2-Ph-O-Ph-C(CH3) (CH3)-Ph-O-]n above-mentioned [to which it comes to blend the polysulfone resin expressed with [however, n means the integer of 1-2000]] (1).) repeatedly with BIIR

(8) Repeat with CIIR and a unit is n (-Ph-SO2-Ph-O-). It is the polysulfone system resin constituent of the above-mentioned (1) publication with which it comes to blend the polysulfone resin expressed with [however, n means the integer of 1-2000].

(9) Repeat with BIIR and a unit is n (-Ph-SO2-Ph-O-Ph-Ph-O-). It is the polysulfone system resin constituent of the above-mentioned (1) publication with which it comes to blend the polysulfone resin expressed with [however, n means the integer of 1-2000].

(10) Repeat with CIIR and a unit is n (-(CH3) (CH3) Ph-SO2-Ph(CH3) (CH3)-O-Ph-CO-Ph-O-). It is the polysulfone system resin constituent of the above-mentioned (1) publication with which it comes to blend the polysulfone resin expressed with [however, n means the integer of 1-2000].

(11) DVIIR, n (-Ph-SO2-Ph-O-) a repeat unit -- [-Ph-SO2-Ph-O-Ph-C(CH3) (CH3)-Ph-O-n -- the polysulfone resin and the repeat unit which are expressed with [however, n means the integer of 1-2000] It is the polysulfone system resin constituent of the above-mentioned (1) publication with which it comes to blend the polysulfone resin expressed with [however, n means the integer of 1-2000].

(12) DVIIR and a repeat unit are n (-Ph-SO2-Ph-O-). The polysulfone resin and the repeat unit which are expressed with [however, n means the integer of 1-2000] are n (-Ph-SO2-Ph-O-Ph-Ph-O-). It is the polysulfone system resin constituent of the above-mentioned (1) publication with which it comes to blend the polysulfone resin expressed with [however, n means the integer of 2-2000].
(13) Repeat with DVIIR and a unit is n (-Ph-SO2-Ph-O-). It is the polysulfone system resin constituent of the above-mentioned (1) publication with which it comes to blend the polysulfone resin expressed with [however, n means the integer of 2-2000].
[Effect of the Invention] the medical application by this invention, and drugs -- an appliance -- an implement does the following effectiveness so.
1) It has the exfoliation of three particles and a rubber fragment, the drug solution leakage, the water repellence, the injection needling resistance, the amount of steam transparency, the gas of a head space, the alkali-proof solution nature, the coefficient of water absorption, and the health nature that was excellent about adsorption of a drug solution which has the high health nature which passes the value of standard of a Japanese pharmacopoeia and which has 2 oxygen transparency barrier nature.

TECHNICAL FIELD

[Industrial Application] the medical application which health nature of this invention is high, for example, uses as instrument ingredients, such as a container, and consists of the suitable new polysulfone system resin constituent for a mothball and this constituent of those contents, and drugs -- an appliance -- it is related with an implement.

PRIOR ART

[Description of the Prior Art] About medical application and the instrument for drugs, the class, the engine performance, quality, the trial item, the examining method, the value of standard, etc. are set to the Pharmaceutical Affairs Law, a Japanese pharmacopoeia, and Notice of the Ministry of Health and Welfare. The product with which the iatrotechnique applied the various values of standard as a want matter to each item, an aforementioned approach, and an aforementioned numeric value further in the ever-advancing time is manufactured like today.
[0003] The transparent raw material used for medical application and drugs is mainly a glass product, and came as an instrument combining the Plastic solid which uses natural rubber as a raw material as an elasticity elastic body for being able to come, and it being alike, for example, sealing. however, recent years -- synthetic resin and synthetic rubber -- medical application and drugs -- an appliance -- it inquires as a raw material of an implement and marketing is also carried out.

EFFECT OF THE INVENTION

[Effect of the Invention] the medical application by this invention, and drugs -- an appliance -- an implement does the following effectiveness so.
1) It has the exfoliation of three particles and a rubber fragment, the drug solution leakage, the water repellence, the injection needling resistance, the amount of steam transparency, the gas of a head space, the alkali-proof solution nature, the coefficient of water absorption, and the health nature that was excellent about adsorption of a drug solution which has the high health nature which passes the value of standard of a Japanese pharmacopoeia and which has 2 oxygen transparency barrier nature.

TECHNICAL PROBLEM

[Problem(s) to be Solved by the Invention] by the way, the medical application and drugs which are conventionally used widely -- an appliance -- there are the following properties and troubles about an implement raw material. Plasticizers, such as stabilizers, such as for example, a tin system added by resin, cadmium, and a zinc salt double salt compound, and dioctyl phthalate, dioctyl adipate, tricresyl phosphate, etc. should elute and pollute a polyvinyl chloride (abbreviated name PVC) in drugs and a drug solution. Environmental destruction may be caused when the resin product other than the PVC raw material monomer remaining in resin is discarded. The product with polyethylene (abbreviated name PE) made [with a product] from it because softening temperature is low serves as an instrument which cannot carry out high-pressure steam sterilization. Pasteurization is difficult although high-pressure steam sterilization can do polypropylene (abbreviated name PP). There is a report which denaturalized, made resin transparence and used it as medical-application raw material (JP,3-163144,A, said 3-28246 each number official report). Although PE and PP are comparatively excellent in the permeability-proof over moisture and humidity, gas cutoff nature, such as oxygen and carbon dioxide gas, is bad, and a content drug has the problem oxidized and discolored. As an approach of improving the fault of such PE and PP [whether ethylene and the saponification object (abbreviated name EVOH) of a vinyl acetate copolymerization component are mixed with PE and PP, and] or making it the package object which carried out the laminating to PE, PP, and EVOH is proposed (for example, "package film --) practical use thermal-resistance:plastics age of a shaping container and a bottle No. 6 (1992) "high barrier multilayer plastic envelope: Pharmaceutical factory vol.6, No.12 (1986)", "The gas barrier nature container of plastics, the gas barrier nature of plastics, and container shaping approach:hood packaging vol.32-No.3", "high gas barrier nature wrapping : Plastics vol.38, No.5" (1987), The application and the actual condition to "barrier nature resin container : Plastics vol.27, No.5" (1977), "barrier nature composite material and PVDC : KOMPA tech vol.15, No.1" (1987), Barrier resin which functionalizes "packing material : KOMPA tech vol.17, No.6(1989)", The "latest functional wrapping : Industrial ingredient vol.37, No.14(1989)", The trend of the "latest functional container: Since water absorption and hygroscopicity of EVOH are very strong, when humidity and moisture live [science, industrial vol.61-4 (1987)", etc.] together at the time of high-pressure steam sterilization etc., it has the fault that gas electric shielding validity, such as oxygen and air, is very weak. Although a glass raw material is a raw material excellent in a heatproof, an acid-proof history, transparency, etc., there is a trouble that the alkali generated from a glass front face and the particle which exfoliates from glass pollute a chemical and a drug solution. There are problems,

such as an offensive odor and formaldehyde generating, from the resin of polyphenylene ether resin (abbreviated name PFE), polyethylene terephthalate (abbreviated name PET), polybutylene terephthalate (abbreviated name PBT), and a polycarbonate (abbreviated name PC). In case natural rubber (abbreviated name NR) and the polyisoprene rubber (abbreviated name IR) of synthetic rubber, butadiene rubber (abbreviated name BR), styrene butadiene rubber (abbreviated name SBR), nitrile rubber (abbreviated name NBR), isobutylene isoprene rubber (abbreviated name IIR), halogenation isobutylene isoprene rubber (BIIR, CIIR), etc. are used for medical application and drugs, they have the trouble that the vulcanizing agent, vulcanization accelerator, and reinforcing agent which vulcanize rubber cause elution, exfoliation, etc., and pollute a chemical and a drug solution. this invention persons have proposed the rubber goods (JP,5-43740,B) which already blended the polyethylene of ultrahigh molecular weight with IR, BR, and SBR, and the rubber goods (JP,4-213347,A) which combined the special vulcanizing agent with IIR. the medical application and drugs using the new raw material with which this invention canceled the fault of elegance conventionally -- an appliance -- the medical application which consists of the new polysulfone system resin constituent and new it which especially health nature is high, it uses for instruments, such as a container, and there are no pollutant elution, exfoliation, etc. to contents for the purpose of offer of an implement, and were suitable for the mothball of contents, and drugs -- an appliance -- it has the intention of an implement.

MEANS

[Means for Solving the Problem] This invention offers the polysulfone system resin constituent which comes to contain an isobutylene-isoprene copolymerization system elastic body and polysulfone system resin as The means for solving a technical problem. As a desirable mode in this invention, the polysulfone system resin constituent which is the mixture or the alloy ghost of one or more sorts of an isobutylene-isoprene copolymerization system elastic body and polysulfone system resin which comes to contain one or more sorts is mentioned especially. moreover -- as the especially desirable mode in this invention -- this polysulfone system resin -- n (-Ph-SO2-Ph-S-) The thing which makes it a unit repeatedly [however, for n to mean the integer of 2-1000], or (-Ph-SO2-Ph-0-) n what makes it a unit repeatedly [however, for n to mean the integer of 2-1000] -- it comes out and a certain thing is mentioned. the medical application which consists of a polysulfone system resin constituent with which this invention comes to contain the isobutylene-isoprene copolymerization system elastic body and polysulfone system resin of this invention further described above, and drugs -- an appliance -- an implement is offered. A plug is especially mentioned as a desirable mode of the medical application of this invention, and the instrument for drugs. furthermore, the medical application of this invention and drugs -- an appliance -- it is also an especially desirable mode that an implement is a syringe, an infusion set, or a container.

OPERATION

[Function] The isobutylene-isoprene copolymerization system elastic body concerning this invention (it may abbreviate to an IIR elastic body hereafter), It is the generic name of rubber

(BIIR) and isobutylene-isoprene-divinylbenzene copolymerization rubber (abbreviated name DVIIR) for which the bromine was made to react to the rubber (CIIR) and isobutylene-isoprene copolymerization rubber which made chlorine react to isobutylene-isoprene copolymerization rubber (IIR) and isobutylene-isoprene copolymerization rubber, and is the elastic body which comes to vulcanize IIR, CIIR, BIIR, and DVIIR using one or more sorts chosen from a vulcanizing agent, for example, sulfur, a zinc white, magnesium, an amine compound, organic peroxide a MAIMIDO compound,

[0007] the IIR elastic body concerning this invention -- 4.5 or less % of the weight of isoprene radical contents, and average molecular weight 10,000-650,000 it is -- for example, the 100 weight sections of IIR -- receiving Sulfur, for example, t-butylperoxy isopropyl, n-butyl -4, 4'-screw (t-butyl peroxide) valerate, Organic peroxide, such as 1 and 1-JI (t-butylperoxy) 3 and 3 and a 5-trimethyl cyclohexane, For example, maleimide, such as N and N'-m-phenylene bismaleimide A vulcanizing agent and dipentamethylenethiuramtetrasulfide, such as a zinc white, It can manufacture with the well-known means of vulcanizing vulcanization accelerators, such as zinc diethyldithiocarbamate, tetramethylthiurammonosulfide, and tetramethylthiuramdisulfide, 0.5 - 2 weight section, in addition by carrying out heating application of pressure, for example.

[0008] The elastic body of BIIR and CIIR concerning this invention can be manufactured by carrying out 1-5 weight section addition, and heating and pressurizing vulcanizing agents, such as a zinc white and magnesium oxide, for example, the organic amine compound which has an amino group and a carboxyl group in intramolecular, the same vulcanization accelerator as the case of said IIR elastic body, etc. to the 100 weight sections of BIIR and CIIR.

[0009] The elastic body of DVIIR concerning this invention can be manufactured by carrying out 0.5-2 weight section combination, heating and pressurizing the same organic peroxide as the elastic body of IIR, and a case, and vulcanizing it to the DVIIR100 weight section.

[0010] As preparation of vulcanization of the elastic body concerning this invention, and the resin constituent of this invention, and the concrete technique of shaping from this constituent, After performing dynamic vulcanization pressurized and heated at 160-220 degrees C with an internal mixer or a mixed extruding machine after mixing the various above compounding agents beforehand to crude rubber, it can mix to polysulfone resin or mixing, the approach of alloy-izing, or the approach of blending the vulcanization accelerator other than a vulcanizing agent, blending a polysulfone acid further, and carrying out shaping vulcanization within metal mold can be adopted.

[0011] The polysulfone system resin concerning this invention is resin of the super-macromolecule object which used association with an aromatic series system hydrocarbon group and a sulfonyl group (-SO2-) as the principal component. A phenyl group and a phenylene group are mentioned as this aromatic hydrocarbon radical. The phenyl group or phenylene group combined with one sulfonyl group has one case and 2-7 things, and when it is the latter, they is a biphenyl radical, a bis-phenyl alkane radical, a triphenyl radical, etc. Moreover, the polysulfone system resin of this invention can have low-grade alkyl groups other than a phenyl group, a phenylene group, or a sulfonyl group, such as an oxy-radical (-O-), a thio radical (-S-), a carbonyl group (-CO-), and a methyl group, as a constituent.

[0012] The example of the repeat unit of the polysulfone system resin concerning this invention is given to below. In the following example a-w, a code means as follows. Ph: -- phenyl group or phenylene group, and -SO2-: -- a sulfonyl group, a -O-:oxy-radical, a -S-:thio radical, a -CO-:carbonyl group, and a CH3-:methyl group. n: Integer a of 2-1000 : (-Ph-SO2) -)nb:(-Ph-SO2 -

Ph-)nc:(-Ph-SO2 -Ph-Ph-SO2 -Ph)nd:(-Ph-SO2 -Ph-Ph-Ph-SO2 -Ph)ne:(-Ph-SO2 -Ph-Ph-Ph-SO2 -)nf:(-Ph-SO2 -Ph-O-)ng:(-Ph-SO2 -Ph-SO2 -Ph-O-)nh:(-Ph-SO2 -Ph-SO2 -Ph-O-Ph-O-)ni:(-Ph-SO2 -Ph-PhSO2 -Ph-O-)nj:(-Ph-SO2 -Ph-Ph-SO2 -Ph-O-Ph-O-)nk:(-Ph-SO2-Ph-Ph-SO2-Ph-O-Ph-Ph-O-) nl:(-Ph-SO2-Ph-Ph-O-Ph-O-) nm : () [-Ph-SO2] - Ph-O-Ph-O-Ph-O-nn:(-Ph-SO2-Ph-O-Ph-Ph-O-) no:(-Ph-SO2-Ph-CH2-Ph-SO2-Ph-O-) np:[-Ph-SO2-Ph-Ph-O-Ph-C () [CH3] -Ph-O-]nq:[-Ph-SO2 (CH3) - Ph-O-Ph-C(Ph) (Ph)-Ph-O-]nr:(-Ph-SO2-Ph-S-) ns:(-Ph-SO2-Ph-O-Ph-CO-Ph-O -) nt:(-Ph-SO2-Ph-O-Ph-O-) nu:[-Ph-SO2 - Ph-O-Ph-C(CH3) (CH3)-Ph-O-:[ ]nv:(-Ph-Ph-SO2-Ph-Ph-SO2-Ph-O-) nw] [-(CH3) (CH3)-Ph-SO2-Ph(CH3) (CH3)-O-Ph-CO-Ph-O-] n [0013] The polysulfone system resin concerning this invention is a polymer which uses as a principal component a repeat unit which was described above. A conventionally well-known technique, for example, JP,45-21318,B -- said -- 46-21458 -- said -- 47-617 -- said -- 53-25879 -- said -- 56-2091 -- said -- 61-12930 and JP,52-96700,A -- said -- 53-10696 -- said -- 59-12930 -- said -- 63-21030 -- said -- 63-243128 -- JP,1-315422,A -- said -- 1-318040 -- said -- 3-41120 -- said -- 3-95200 -- said -- the technique indicated by 4-335030, said 5-9453 each number official report, etc. A polymerization is carried out and it can manufacture. average molecular weight of this polysulfone system resin 5,000-950,000 it is -- many carrying-out [using an alkaline catalyst]-in polar organic solvent-polymerization of this resin approaches are adopted. However, as for the polysulfone system resin used for this invention, what repeated solvent washing, warm water washing, etc. and removed a raw material compound, the oligomer of low molecular weight, an inorganic compound (many are NaCl), etc. as much as possible is desirable. Various kinds of well-known techniques are applicable to the purification means of such this polysulfone system resin. It is tough nature, high intensity, thermal resistance, KUREBU-proof nature, and abrasion resistance, and the polysulfone acid system resin concerning this invention is resin of a frank color and transparency, it has the resistance excellent also in an acid, alkali, and salting in liquid, and can also bear the high temperature service in the inside of a detergent and a hydrocarbon. furthermore -- since it has the property that it can be repeatedly equal also to 130 degrees C and the autoclave sterilization for 30 minutes with steam-proof and hot water resistance -- medical application and drugs -- an appliance -- it uses for an implement and is dramatically advantageous.

[0014] In addition, what added the stabilizer of the amount of macromolecules comparatively as polysulfone acid resin of this invention is desirable. As such a stabilizer **, for example, tetrakis [methylene (3, 5-G t-butyl-4-hydroxyphenyl) propionate] methane, : Trade name IRUGA NOx 1010 (Ciba-Geigy make), Triethylene glycol-bis--3-(2-t-butyl-4-hydroxy-5-methylphenyl) propionate : Trade name IRUGA NOx 245 (Ciba-Geigy make), Screw (2, 6-G t-butyl-4-methylphenyl) PENTA ERIS toll diphosphite : Trade name ADEO stub PEP-36 (product made from Asahi Electrification), It is desirable for N and N'-m-phenylene bismaleimide, a tocopherol, etc. to be mentioned and to carry out 0.01-0.5 weight section addition of these one or more kinds to this polysulfone acid resin 100 weight section.

[0015] The constituent of this invention comes to contain the above-mentioned IIR elastic body and polysulfone system resin. Moreover, this IIR elastic body and polysulfone system resin can also blend one or more sorts respectively. Polysulfone acid system resin is preferably blended in 95 - 5% of the weight of the range 99 to 1% of the weight to an IIR elastic body. this blending ratio of coal -- medical application and drugs -- an appliance -- it is desirable to choose corresponding to the class of implement and the hard and soft degree suitable for that instrument. For example, when applying as an instrument plug for medical application and drugs, it is desirable to carry out 5-40 weight section combination of the polysulfone acid system resin to

the IIR elastic body 100 weight section. It is 5 - 30 weight section especially preferably. This is because the physical characteristic as a plug, for example, the physical characteristic needed in the case of injection needling, will be lacked under in 5 weight sections when it cannot acquire to the desired end, suitable property, for example, elasticity, but 40 weight sections are exceeded. moreover, medical application and drugs -- an appliance -- the elastic body chosen from BIIR, CIIR, and DVIIR to the polysulfone acid 100 weight section when using it for the body of a container of an implement etc. -- the 2 - 100 weight section -- desirable -- 5 - 50 weight section -- mixing -- or it alloy-izes. the resin object of thermal resistance and high elasticity -- becoming -- a medical-application instrument and drugs -- an appliance -- as an implement, thermal resistance is high, therefore serves as the container and instrument which repeat heat sterilization, high voltage auto KUREBU sterilization, and ethyleneoxide sterilization, and can perform them. Therefore, it fabricates and is suitable for the instrument for an operation, a syringe, a syringe-cum-a container, etc. Moreover, it could be made the film, and could use for raw materials, such as bags for infusion solutions, and it became clear that it could use suitable for the preservation container of the high TARORI transfusions containing grape sugar and amino acid etc. In this film shaping, it is desirable to mix processing aid, a graft copolymer, etc. to the constituent of this invention.

[0016] The constituent which consists of the IIR elastic body and polysulfone resin of this invention as mentioned above may be mixture, and can also be made into an alloy ghost. Moreover, processing aid can be added in order to make the workability of mixture and an alloy ghost, and a moldability good. As such processing aid, for example Higher-fatty-acids:, for example, arachin acid, Metal soap:, for example, zinc stearate, calcium stearates, such as behenic acid, Fatty-acid amides:, for example, styrene bis-stearyl amides, such as an aluminum stearate salt, Ethylene bis-oleic amide, a behenic acid amide, octadecanamide, etc., Higher-fatty-acid ester:, for example, long-chain-fatty-acid ester of 20-24 carbon numbers, Wax:, for example, a micro crystallin wax, such as a sorbitan fatty acid ester The amount polyethylene of giant molecules, alcohols of 16-18 carbon numbers, such as polyethylene wax, One or more kinds, such as silicone oils, below 10 weight sections, a graft copolymer, a block copolymer (for example, the hydrogenation object of a styrene-butadiene-rubber-block copolymer and this copolymer --) a poly dimethylsiloxane-polyethylene oxide block copolymer, an ethylene-glycidyl methacrylate graft copolymer, etc. -- etc. -- from -- blending one or more kinds chosen below 20 weight sections It can consider as a very uniform alloy ghost, and workability can be improved.

[0017] As a means to mix and knead the IIR elastic body and polysulfone system resin concerning this invention, and to alloy-ize them, conventionally, using well-known equipment, for example, an internal mixer, one shaft, or a twin screw extruder, it can carry out at the temperature of 120-380 degrees C, and becomes uniform mixture and an alloy ghost. moreover -- as it is -- extrusion molding -- carrying out -- medical application and drugs -- an appliance -- it can also consider as an implement. the medical application concerning this invention, and drugs -- an appliance -- the product fabricated as an implement -- each -- 48. test for rubber closure for aqueous infusions of a Japanese pharmacopoeia (the 12th amendment), the plastic envelope examining method for 49. infusion solutions, and Notice of the Ministry of Health and Welfare No. 301 -- said -- No. 413 -- said -- the medical application which suits No. 442, and drugs -- an appliance -- it is an implement and can consider as a syringe, a syringe-cum-a container, and an infusion set instrument. Moreover, it becomes drugs and the container which has the outstanding

description that the quality can be held for a content chemical over a long period of time as a container of a drug solution.

EXAMPLE

[Example] Hereafter, although an example explains this invention to a detail, this invention is not limited to these.
[Polymerization:1 which is the Pol sulfonic acid] NaHS(47 % of the weight of concentration) 358g, NaOH(48 % of the weight of concentration) 225g, CH3 COONa123g, Na2 CO3 19g, and N-methyl pyrrolidone 2376g are taught to a 10,000ml autoclave, and it agitates at the temperature of 130 degrees C for 3 hours, passing nitrogen gas. After cooling the mixture at 70 degrees C, it mixes agitating N-methyl pyrrolidones 297g and 4 and 4-dichloro diphenylsulfone 878.5g mixture in this reactant, it heats at the temperature of 260 degrees C for 4 hours, and a polymerization is performed. next -- while cooling agitating to 120 degrees C with 1-degree-C speed for /and agitating in 9g [of acetic acids], and N-methyl pyrrolidone 2583g -- gradual -- slushing -- a polymer -- a particle -- after making it deposit as powdered and carrying out a ** exception -- 1500ml of 70-degree C warm water -- washing -- it washes in methanol 1000ml further. It is IRUGA NOx 1010 to the obtained polymer 100 weight section. It dries in a vacuum after adding the 0.1 weight sections. It was the amount of resin of 632g and glass transition temperature of 192 degrees C which were obtained. The repeat unit of this resin was n (-Ph-SO2-Ph-S-) r, i.e., the above mentioned repeat unit, in light yellow transparence. This resin is abbreviated to Resin r.
[0019] The [examples 1-3 and the example 1 of a comparison, and 2] IIR[trade name The 2.0-mol % and ML1+8 100 ** 42]100 weight section is received whenever [JSR Butyl 365, Japan Synthetic Rubber Co., Ltd. make, and partial saturation]. the ratio (the section in a table means the weight section) which shows polysulfone resin r obtained above in the following table 1 -- blending -- an internal mixer and a twin screw extruder -- kneading -- 2 rolls -- ****(ing) -- combination -- the ground was created.
[0020]
[A table 1]

[0021] ** of the above-mentioned table 1 - ** are as follows.

** PE : low density polyethylene, show REXX M222, the Showa Denko K.K. make, 92 degrees C of softening temperatures.
** Bulking agent : trade name Whitetex:Southern Product made from Clay.
** 2, the 5-dimethyl -2, 5-JI (t-butylperoxy) hexane.
** N and N'-m-phenylene bismaleimide.
** Micro crystallin wax (melting point of 110 degrees F, NIPPON SEIRO CO., LTD. make).
** gamma-mercaptotrimethoxysilane : Nippon Unicar make A-189 (trade name).
[0022] the combination obtained above -- the ground with an oscillating disk rheometer (O. it being called R.R. for short) testing machine Society of Rubber Industry, Japan -- VOL.40 (1967) -- p874 and ASTM D-2705 and SRIS 3102 A minute angle oscillation (torsional oscillation) of an oscillating-type vulcanization trial [revolution reciprocating motion is given. the -- corresponding -- stress -- torque value -- ****** -- measuring -- torque -- a peak price -- (-- c --) -- asking -- this -- torque -- the minimum value -- (-- b --) -- a difference -- asking --] -- carrying out -- the result -- a table 2 -- collecting -- being shown .
[0023]
[A table 2]

[0024] Since an example 1 has the difference of torque value [(c)-(b)] larger than the ground of the example 1 of a comparison, and the example 2 of a comparison and hardness is also large as shown in a table 2, it turns out that rubber is a high elasticity object. Moreover, in the example 2 which increased the quantity of Resin A, and the example 3 which added the silane coupling agent, the addition effectiveness shows torque value higher than an example 1 and Hs value, respectively.
[0025] next, it obtained above -- each -- the rubber stopper for drugs shown in drawing 1 was fabricated by the vulcanization condition:temperature of 170 degrees C, and : during 10 minutes using the ground. In addition, a carboy 2 is capped with a rubber stopper 1, the condition that the aluminium cap 4 wound and fastened is shown, in 3, drawing 1 is the outline sectional view of one example which applied this rubber stopper to the carboy, and, as for drugs and 5, 7 shows [needle admission into a club and 6 show a head space, and] a hypodermic needle. The special health trial which the examining methods and this invention persons of the 12th amendment Japanese pharmacopoeia are using about each rubber stopper was performed. The result is shown in a table 3 and a table 4. A special health trial is performed as follows.

[0026] The other special amounts of health trial particles (trial of the particle weight generated from a rubber stopper); ten rubber stoppers are put in into a hard-glass bottle, it vibrates on a package with a film and 300ml of non-**** and container opening are vibrated for 20 seconds with 2 revolutions-per-second extent by hand. After putting after that for 1 hour, the number of an underwater particle is measured with an optical electric shielding mold automatic particle measuring instrument (product made from HIAC). In addition, since existence of the particle 5 micrometers or more in a parenteral solution causes the problem of blockading a blood vessel, it serves as a critical item.
[0027] Exfoliation of a rubber fragment (Fragmentation); 5ml of water is put into the bottle (10ml capacity) of the configuration shown in drawing 1 as 2, a rubber stopper 1 is capped, and then an aluminium cap 4 is rolled and fastened. 2ml water is put into the glass syringe which attached the trial needle [22G (0.70x32mm)], and the needle admission into a club 5 of a rubber stopper is made to penetrate this 20 times. A hypodermic needle is drawn out after pouring in the water in a glass syringe into a bottle at the time of the 20th penetration. After vibrating the inside of a bottle, a rubber stopper is removed, content liquid is filtered and the rubber piece number on a filter paper is counted. Although an exam method is what improved the approach of the British standard 3263 (it abbreviates to BS) and the specification of BS is three or less rubber pieces, less than two pieces are demanded in this current this industry.
[0028] Drug solution leakage; 500ml of water is put into the bottle 2 of drawing 1 , a rubber stopper 1 is capped, and an aluminium cap 4 is rolled and fastened. Leave it for 1 hour, running through with the rocket needle 7 (the JMS nature No. 200, rocket needle with an infusion set) from the needle admission into a club 5 of the rubber stopper after heating this for 30 minutes at 121 degrees C within a container, and maintaining a bottle at a handstand condition, then stab with a vent wire, 400ml of water in a bottle is made to flow out, the liquid spill at drawing and this time (ml) is observed for the rocket needle from a rubber stopper at this event, and it measures.
[0029] Water repellence (Water repellency); 500ml of distilled water is put into the bottle 2 of drawing 1 , a rubber stopper 1 is capped, and an aluminium cap 4 is rolled and fastened. Next, a bottle wall is observed, after putting into a proof-pressure heating container, steaming for 30 minutes at the temperature of 121 degrees C and leaving it in a room temperature for 24 hours. What does not accept waterdrop at this time is considered as acceptance.
[0030] Injection needling resistance-force trial (Determination of penetrability); the force in case a hypodermic needle 7 (21. the S.W.G. outer diameter of 0.81mm, die length of 38mm) penetrates a rubber stopper the rate for 20cm/is measured with a measurement machine (tension form spreading tension testing machine), and it considers as acceptance by 0.5 kg. An exam is amelioration of the trial to which BS is equivalent. BS value of standard passes by 1000g or less.
[0031] 8ml of brine solutions is put in 2% of the weight into the carboy of the steam permeability test chart 1 , a rubber stopper 1 is capped, and an aluminium cap 4 is rolled and fastened further. Change of weight is measured after preservation for six months at a room temperature in the desiccator into which silica gel was put for this glass bottle, and the amount of steam transparency of a rubber stopper (g) is measured. The five averages are taken and 1g or less is considered as acceptance. It is this invention persons' independence specification testing.
[0032] 8ml of brine solutions is put in 2% of the weight into the carboy 2 of gas-constituents trial drawing 1 in a head space, a rubber stopper 1 is capped, and an aluminium cap 4 is rolled and fastened further. It is left for about 10 hours, after carrying out steamy heating of this carboy for 60 minutes at the temperature of 121**1 degree C with a proof-pressure container. Next, gas 5ml

of the head space 6 in a bottle is extracted in the syringe for gas, and this is measured in gas chromatography. Column: See the existence of the peak of a part for 101 (180-200 mesh WHP) and carrier gas helium50ml/, and 10%OV-temperature [column / of 100-200 degrees C (4 degree-C temperature up / A part for //)] **, and size. An exam is a trial which investigates the ultralow volume generation of gas by the rubber and the compounding agent which have been a problem in recent years.

[0033] Alkali-proof solution trial; ten rubber stoppers are put into an alkali-proof container, and it is sodium carbonate 0.5 of the amount of 10 times of rubber stopper weight. After adding a weight % solution, this rubber stopper is capped, and an aluminium cap is rolled and fastened. Next, steamy heating is carried out for 30 minutes at the temperature of 121 degrees C with a high pressure vessel. Except for the rubber stopper after neglect and cooling, the wavelength of 430nm and the permeability of a 650nm visible region are measured for test fluid in a quartz cell to a room temperature. 95% or more is considered as acceptance. the fundamental trial whose exam examines the relation between rubber and a drug solution -- the rubber goods with low permeability -- adoption -- it is unsuitable.

[0034] Water absorption test; the rubber goods which carried out bridge formation shaping are dried by temperature the ordinary pressure of 105 degrees C for 3 hours. Next, it is the weight (A) after about 1-hour neglect in the desiccator containing a desiccating agent. It weighs precisely. Next, it dips into the purified water of the amount of 10 times of this rubber stopper, and steamy heating is carried out for 30 minutes the temperature of 121**1 degree C within a proof-pressure container as it is. After cooling, only a rubber stopper is left for 30 minutes in a desiccator, surface water is taken, and it is the weight at that time (B). It weighs precisely, and asks for (([(B)-(A)/(A)] x100) %), and 2 or less % of the weight is considered as acceptance.

[0035] The adsorption test of a drug solution; nitric-acid iso SORUBITO (the medicine for ischemic heart disease, the melting point of 72 degrees C, product made from Japanese-made medicine) was diluted with the physiological saline, and as 0.040 % of the weight, 3ml of this liquid was put into the 10ml bottle 2 at accuracy, the rubber stopper was capped, the aluminium cap was rolled, and it was left in the state of the handstand in total for 24 hours. This is applied to a high-speed liquid chromatograph (product made from HLPC), the amount of nitric-acid iso SORUBITO is measured and the loss in quantity which adsorbed is obtained. Column: FINEPAK SILC18 (a trade name, Jasco make), a mobile-phase methanol: Water = 7:3 and 1ml [of the rates of flow] a part for /, detector UVIDEC100-IV (a trade name, the Jasco make, 220nm)

[0036]

[A table 3]

[0037]
[A table 4]

[0038] As shown in a table 3 and a table 4, all this invention articles conform to the value of standard of the 12th amendment Japanese pharmacopoeia. In addition to it, it turns out that they are the container which can respond to the newest drugs, and the outstanding rubber stopper

which can also suit the special independence trial item as an instrument. On the other hand, the product of the examples 1 and 2 of a comparison shows the result which poses a problem in several items, such as pH, a residue on evaporation, and the amount of particles.
[0039] [Example 4] The BIIR(product [made from EXXON CHEMICAL], ML1+8 125 degree-C 50, 0.6 % of the weight of bromine contents) 100 weight section, 1.0 weight sections [made from an active white (Sakai Chemical Industry stock)], N, and N'-m-phenylene bismaleimide (Kawaguchi Chemical Industry Co., Ltd. make) 2.0 weight section, insoluble sulfur (after mixing the 0.2 weight section made from Japanese Dry distillation with an internal mixer, kneading was performed for 7 minutes at the temperature of 160 degrees C, and it considered as dynamic vulcanizate.) the polysulfone resin (it POLYSULFONE(s) trade name UDEL [ ] --) refined independently the Union Carbide repeat unit -- said u:[-Ph-SO2-Ph-O-Ph-C(CH3) (CH3)-Ph-O-] n N-methyl pyrrolidone : The thing]100 weight section washed twice with the solvent which comes to heat water =1:0.5, The ethylene bis-octadecanamide (Nippon Kasei Chemical Co., Ltd. make) 1 weight section, It is the maleic-anhydride 5 weight section about a styrene-butadiene-ethylene copolymer. The block-copolymer (prototype) 5 weight section was made into the alloy ghost at the temperature of 160-220 degrees C with the internal mixer and the 2 ream type extruder. Next, it considered as the uniform film plate through T Thailand. 0.4mm in thickness JIS the place which are the tensile strength of 213kg/cm2, and 210% of elongation, and measured the amount of oxygen gas transparency as a result of measuring a physical property based on K6301 (product made from Yanamoto factory GTR) -- the temperature of 20 degrees C, and dryness -- 100cc[/m] 2 and 24 hrs/atm it was . the amount of oxygen gas transparency of the film plate which BIIR before kneading vulcanized -- 300 cc/m2 and 24 hrs/atm it was -- according to this invention, by mixing polysulfone resin with an IIR elastic body shows from things that the gas barrier nature to oxygen was improved. In addition, the trial based on the plastic envelope examining method for 49. infusion solutions of the 12th amendment Japanese pharmacopoeia about the alloy ghost of BIIR of this invention and polysulfone acid resin is performed, and the result is shown in the after-mentioned table 5.
[0040] [Example 5] After mixing the CIIR(JSR CHLOROBUTYL 1068, trade name, Japan Synthetic Rubber Co., Ltd. make, ML1+8 125 degree-C 50, 1.2 % of the weight of halogen contents) 100 weight section, the active white (Sakai Chemical Industry Co., Ltd. make) 1.0 weight section, and the zinc-diethyldithiocarbamate 1.0 weight section with an internal mixer, kneading was performed for 7 minutes at the temperature of 160 degrees C, and it considered as dynamic vulcanizate. Polysulfone acid [trade name VICTREX PES, the product made from ICI which were refined independently, A repeat unit is said f:(-Ph-SO2-Ph-O-) n. A thing tetrahydrofuran: -- water: -- the thing]400 weight section further washed with the acetone after washing with the solvent which acetic-acid =20:5:0.1 heated -- The styrene-ethylene-styrene block-copolymer (Shilu chemical company treatment article) 10 weight section, The polyethylene terephthalate (polyethylene terephthalate [by Kuraray Co., Ltd.], grade KS700) 30 weight section was made into the alloy ghost at the temperature of 160-220 degrees C with the internal mixer and the 2 ream type extruder. Next, it considered as the uniform film plate with a thickness of 0.4mm through T Thailand. this film -- JIS physical based on K6301 -- the place which are the tensile strength of 256kg/cm2, and 180% of elongation, and measured the amount of oxygen gas transparency like the example 4 as a result of measuring a characteristic -- 85 cc/m2 and 24 hrs/atm it was . The created transfusions container is shown in drawing 2 . In drawing 2 , in the container regio oralis and 10, a joining plug and 11 express a heat welding and 12 expresses [8 / a parenteral solution and 9] ******. In addition, the trial based on the plastic

envelope examining method for 49. infusion solutions of the 12th amendment Japanese pharmacopoeia is performed, and the result is united and shown in the after-mentioned table 5. As shown in a table 5, the product by this invention has passed the value of standard of the 12th amendment Japanese pharmacopoeia.

[0041]

[A table 5]

[0042] [Polymerization:2 which is a polysulfone acid] It is a screw (3, 5-dimethyl-4-hydroxyphenyl) sulfone to a 3000ml three necked flask. 306g (one mol), Chlorobenzene 1000ml and sulfolane 450ml are added and stirred. To the bottom of nitrogen-gas-atmosphere mind, heat at 60 degrees C and 250.5g of NaOH (45 % of the weight) solutions is added gradually. 50ml purified water is added, if heating is continued to the temperature of 120-140 degrees C and a reactant amounts to 145 degrees C except for chlorobenzene with azeotropy, it will cool at 130 degrees C, and it is a screw (4-fluoro phenyl) ketone. 218g is added and it reacts at 200 degrees C for 8 hours. It cooled, and the polymerization reaction object filled the bottom of stirring with a lot of methanols, deposited resin, was filtered, and washed and carried out the vacuum drying with an acetone and warm water. The amount of resin of 450g Repeat unit w:[-(CH3) (CH3) Ph-SO2-Ph(CH3) (CH3)-O-Ph-CO-Ph-O-] n, glass transition temperature of 240 degrees C. This resin is abbreviated to Resin w.

[0043] [Polymerization:3 which is a polysulfone acid] 4 and 4'-diphenolg [149] and 4 and 4'-dichloro diphenylsulfone 234g, 121.6g [of anhydrous potassium carbonate], N, and N'-dimethylacetamide 1200g is taught to a 4000ml three necked flask, the inside of a reactor is made into nitrogen-gas-atmosphere mind, is boiled, and N and N'-dimethylacetamide and water are made to flow out. After performing a polymerization reaction for about 4 hours, it cools, potassium carbonate is carried out a ** exception, the bottom of stirring is filled with a lot of methanols, a resin object is deposited, a methanol and warm water wash, and a vacuum drying is performed. The obtained amount of resin is 340g. Glass transition temperature of 220 degrees C. this resin -- a repeat unit -- said n:(-Ph-SO2-Ph-O-Ph-Ph-O-) n it is -- this resin is abbreviated to

Resin n.
[0044] [Examples 6-10] It blended with the ratio (weight section) shown in a table 6 about various kinds of polysulfone resin and IIR elastic bodies. After mixing with each raw material powder beforehand, it fabricated in the glass syringe configuration shown in drawing 3 after dynamic vulcanization at the extruder temperature of 180-220 degrees C. In drawing 3 , in a glass syringe and 14, **** and 15 express a hypodermic needle and 16 expresses [13] ******. Based on Notice of the Ministry of Health and Welfare No. 442, it examined about the obtained glass syringe. A result is shown in a table 7.
[0045]
[A table 6]

[0046]
[A table 7]

[0047] As polysulfone acid system resin, in this invention, the combination of either of the one or more sort all kinds of polysulfone system resin and either of the one or more sort all kinds of IIR has [any one sort and the IIR elastic body of the resin of r, n, w, u, and f] similarly it. [repeatedly effective in the above this invention example, although the unit showed the example of the combination which is IIR, BIIR, CIIR, or one sort of DVIIR each] It consists of combination with either of one sort thru/or all the kinds of either of the polysulfone acids of the one sort a unit is [sort] among a-w thru/or all the kinds specifically described above, IIR and BIIR, CIIR, and the DVIIR(s) repeatedly.
[0048] It is shown in the form where the embodiment of this invention was summarized, below.
(1) The polysulfone system resin constituent which comes to contain 95 - 5% of the weight more than per sort of an isobutylene-isoprene copolymerization system elastic body, and 5 - 95% of the weight more than per sort of polysulfone system resin.
(2) the medical application which consists of a polysulfone system resin constituent which comes to carry out 5-40 weight section combination of the polysulfone system resin to the one or more sort 100 weight section of an isobutylene-isoprene copolymerization system elastic body, and drugs -- an appliance -- an implement plug.
(3) the medical application which consists of a polysulfone system resin constituent which comes to carry out 5-30 weight section combination of the polysulfone system resin to the one or more sort 100 weight section of an isobutylene-isoprene copolymerization system elastic body, and drugs -- an appliance -- an implement plug.
(4) the medical application which consists of a polysulfone system resin constituent which comes to carry out 2-100 weight section combination of the one or more sorts of an isobutylene-isoprene copolymerization system elastic body to the one or more sort 100 weight section of polysulfone system resin, and drugs -- an appliance -- an implement.
(5) the medical application which consists of a polysulfone system resin constituent which comes to carry out 5-50 weight section combination of the one or more sorts of an isobutylene-isoprene copolymerization system elastic body to the one or more sort 100 weight section of polysulfone system resin, and drugs -- an appliance -- an implement.
(6) Repeat with IIR and a unit is n (-Ph-SO2-Ph-S-). It is the polysulfone system resin constituent of the above-mentioned (1) publication with which it comes to blend the polysulfone resin expressed with [however, n means the integer of 1-2000].
(7) A unit (polysulfone system resin constituent given in -Ph-SO2-Ph-O-Ph-C(CH3) (CH3)-Ph-

O-]n above-mentioned [to which it comes to blend the polysulfone resin expressed with [however, n means the integer of 1-2000]] (1).) repeatedly with BIIR
(8) Repeat with CIIR and a unit is n (-Ph-SO2-Ph-O-). It is the polysulfone system resin constituent of the above-mentioned (1) publication with which it comes to blend the polysulfone resin expressed with [however, n means the integer of 1-2000].
(9) Repeat with BIIR and a unit is n (-Ph-SO2-Ph-O-Ph-Ph-O-). It is the polysulfone system resin constituent of the above-mentioned (1) publication with which it comes to blend the polysulfone resin expressed with [however, n means the integer of 1-2000].
(10) Repeat with CIIR and a unit is n (-(CH3) (CH3) Ph-SO2-Ph(CH3) (CH3)-O-Ph-CO-Ph-O-). It is the polysulfone system resin constituent of the above-mentioned (1) publication with which it comes to blend the polysulfone resin expressed with [however, n means the integer of 1-2000].
(11) DVIIR, n (-Ph-SO2-Ph-O-) a repeat unit -- [-Ph-SO2-Ph-O-Ph-C(CH3) (CH3)-Ph-O-n -- the polysulfone resin and the repeat unit which are expressed with [however, n means the integer of 1-2000] It is the polysulfone system resin constituent of the above-mentioned (1) publication with which it comes to blend the polysulfone resin expressed with [however, n means the integer of 1-2000].
(12) DVIIR and a repeat unit are n (-Ph-SO2-Ph-O-). The polysulfone resin and the repeat unit which are expressed with [however, n means the integer of 1-2000] are n (-Ph-SO2-Ph-O-Ph-Ph-O-). It is the polysulfone system resin constituent of the above-mentioned (1) publication with which it comes to blend the polysulfone resin expressed with [however, n means the integer of 2-2000].
(13) Repeat with DVIIR and a unit is n (-Ph-SO2-Ph-O-). It is the polysulfone system resin constituent of the above-mentioned (1) publication with which it comes to blend the polysulfone resin expressed with [however, n means the integer of 2-2000].

DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]
[Drawing 1] It is the outline sectional view showing one example which applied the rubber stopper for drug solutions concerning this invention to the carboy.
[Drawing 2] It is the sectional view of the container for infusion solutions concerning this invention.
[Drawing 3] It is the sectional view of the syringe concerning this invention.
[Description of Notations]
1 A rubber stopper, a parenteral solution, the 9 container regio oralis, a 10 joining plug, a 11 heat welding, 12 ******, a 13 glass syringe, 14 ****, a 15 hypodermic needle, 16 ******. 2 Carboy 3 Drugs 4 Aluminum KYUYAPPU 5 Needle admission into a club 6 Head space 7 Hypodermic needle 8